"A COMPARATIVE STUDY ON ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY WITH AND WITHOUT ANTIMICROBIAL THERAPY"

Dissertation Submitted to

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Chennai-600 032

In partial fulfilment of the regulations for the Award of the degree of

M.S. (General Surgery)

Branch – I

MADRAS MEDICAL COLLEGE

CHENNAI

MAY - 2019

CERTIFICATE

This is to certify that, the dissertation entitled "**A COMPARATIVE STUDY ON ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY WITH AND WITHOUT ANTIMICROBIAL THERAPY"** is the bonafide work done by **DR.A.SURESHKUMAR,** during his **M.S. (General Surgery)** course 2016-2019, done under my supervision and is submitted in partial fulfilment of the requirement for the M.S.(BRANCH-I) General Surgery of The Tamil Nadu Dr.MGR Medical University, May 2019 examination.

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DECLARATION

I solemnly declare that this dissertation "**A COMPARATIVE STUDY ON ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY WITH AND WITHOUT ANTIMICROBIAL THERAPY"** was prepared by me at Institute of General surgery, madras medical college and **RAJIV GHANDHI GOVERNMENT GENERAL HOSPITAL, CHENNAI** under the guidance and supervision of **PROF.M.ALLI.M.S.,D.G.O,** professor of general surgery, institute of general surgery, madras medical college, Chennai. This dissertation is submitted to the Tamil Nadu DR.MGR Medical University, Chennai in fulfillment of the university regulation for the award of the degree M.S.General Surgery (branch 1).

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First, I would like to extend my sincere thanks and appreciation towards all our **patients** for their willingness to co-operate with the study.

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CERTIFICATE OF APPROVAL

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Dear Dr.A.Sureshkumar,

The Institutional Ethics Committee has considered your request and approved your study titled **"A COMPARATIVE STUDY ON ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY WITH AND WITHOUT ANTIMICROBIAL THERAPY " - NO.09062017(A)**

The following members of Ethics Committee were present in the meeting hold on **20.06.2017** conducted at Madras Medical College, Chennai 3

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We approve the proposal to be conducted in its presented form.

The Institutional Ethics Committee expects to be informed about the progress of the study and SAE occurring in the course of the study, any changes in the protocol and patients information/informed consent and asks to be provided a copy of the final report.

Member Secretary - Ethics Committee

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INDEX

LIST OF ABBREVIATIONS USED

CHD	Common Hepatic Duct
CBD	Common BileDuct
LC	Laparoscopic Cholecystectomy
CCK	Cholecystokinin
HDL	High Density Lipoproteins
TPN	Total Parenteral Nutrition
USG	Ultrasonography
YAG	Yttrium Aluminium Garnet
COPD	Chronic Obstructive Pulmonary Disease
UDCA	Ursodeoxycholic acid
CDCA	Chenodeoxycholicacid
RHA	Right Hepatic Artery
SSI	Surgical Site Infections

INTRODUCTION

INTRODUCTION

Antibiotic prophylaxis can prevent infection in contaminated wounds but are clearly not indicated for most patients undergoing straightforward clean surgical operations in which no obvious bacterial contamination or insertion of a foreign body has occurred. The infective complications of open cholecystectomy are well known, and prophylactic antibiotics are a routine practice. However, the wounds created after open cholecystectomy behave differently as compared to laparoscopic cholecystectomy. First, the wounds created are smaller as compared to the open surgery. Secondly, it has been proved that the immune system is better preserved in laparoscopic surgery since the tissue trauma is less.These results in lesser activation of the inflammatory response following the laparoscopic procedure. Furthermore, laparoscopic cholecystectomy per se does not violate the mucosal defense barrier of the respiratory, gastro-intestinal or genital epithelium. Observing the low incidence of infections following laparoscopic cholecystectomy, the need for antibiotics is now frequently questioned. The over-use of antibiotics can result in a rising frequency of adverse effects, emergence of drug resistant organisms, as well as increased cost. It is not clear whether antibiotic prophylaxis in laparoscopic cholecystectomy is of any advantage to the patient in terms of preventing infection. Thus, the present study was undertaken to evaluate the rate of infection in laparoscopic cholecystectomies, and to assess the usefulness and efficacy of antibiotic prophylaxis in laparoscopic cholecystectomy.

AIMS AND OBJECTIVE

AIM

To compare the impact of single dose of prophylactic intravenous antibiotic at induction of anaesthesia alone with intravenous antibiotic continued in the post operative period in terms of post-operative infection related complication.

OBJECTIVE

1. To avoid unnecessary long post operative antibiotic regimen
2. To reduce the hospital cost hence we can improve the cost effectiveness
3. To prevent antibiotic resistance

REVIEW OF LITERATURE

REVIEW OF LITERATURE

HISTORICAL REVIEW

Archaeological excavations demonstrating the presence of gallstones in young Egyptian women have confirmed that cholelithiasis has plagued mankind for over 2000 years.[1]

Alexander of Tralles (525-605), a physician of the Byzantine Empire, was one of the first to mention gall stones, describing calculi in human livers.[2]

Gordon Taylor (1937) suggested that the first clinical description of gallstone disease was recorded in the 4th century BC. Despite description of liver and gallbladder, recognition of the gallstones was not recorded until 5th century. Credit is given to Greek Physician Alexandra. His description of concretions within bile ducts is almost certainly that of gallstones.

Vesalius gave an accurate description of human gallstones, concluding that they represented a disease and describing some of their consequences.

Joenisius was credited for the first successful cholecystolithotomy in 1676, but the apparently extracted gallstones from a biliary fistula of the abdominal wall following spontaneous drainage of the abscess.

Cholecystotomy was reported and recommended by Jean- Louis Petit in 1743 after he had mistakenly opened the gall bladder when attempting to drain what he thought was an abdominal wall abscess.

Nonetheless, the treatment for symptomatic gallstone disease remained relatively primitive and ineffective until the late 1800's. As surgical techniques

began to evolve, John Bobbs, an Indian surgeon and others attempted to perform cholecystolithotomy, removing the stone from the gallbladder and leaving the organ in situ. [3] This proved to be effective in ameliorating acute symptoms, physicians were disappointed by the recurrence of symptoms in many of these patients.

In 1882, Karl Langenbunch, a noted German surgeon performed the first successful cholecystectomy.[4]

During the last 100 years, open cholecystectomy has remained the gold standard for the definitive management of patients with symptomatic cholelithiasis.[5]

LAPAROSCOPIC CHOLECYSTECTOMY

Although these advances had widespread rise of laparoscopy for diagnostic and stabilization procedures in gynecological surgery, few general surgeons used it on their surgical practice. The exceptions were pioneering individuals such as George Berci and Alfred Cushiri who used diagnostic laparoscopy for everlasting and staging patients with abdominal malignancies.

In 1987, Philippe Mouret performed the first laparoscopic cholecystectomy in a human.[6]. Almost simultaneously Mc Kernan and Saye performed the first laparoscopic cholecystectomy in the United States in 1988.[7]In fact, in 1985, Prof. Erich Muhe of Boblingen, Germany had carried out the first laparoscopic cholecystectomy. He presented his technique at the Congress of the German Surgical Society.[8] Unfortunately, his technique was not appreciated by his

colleagues and did not become popular. His work was not realized until 1999, when he was recognized by SAGES for having performed the first laparoscopic cholecystectomy. The first laparoscopic cholecystectomy in India was performed in 1990 at the JJ Hospital, Mumbai, followed by few months later in Pune by Dr. Jyotsna Kulkarni. [9]Within a short span of five years laparoscopic cholecystectomy has surpassed conventional cholecystectomy as procedure of choice for diseases of gallbladder

SURGICAL SITE INFECTIONS:

Surgical site infections (SSIs) are infections present in any location along the surgical tract after a surgical procedure. In 1992 the Surgical Wound Infection Task Force published a new set of definitions for wound infections that included changing the term to SSI. Unlike surgical wound infections, SSIs involve postoperative infections occurring at any level (incisional or deep) of a specific procedure. SSIs are divided into incisional superficial (skin, subcutaneous tissue), incisional deep (fascial plane and muscles), and organ/space related (anatomic location of the procedure itself).Examples of organ/space SSIs include intra-abdominal abscesses, empyema, and mediastinitis. SSIs are the most common nosocomial infection in our population and constitute 38% of all infections in surgical patients. By definition, they can occur anytime from 0 to 30 days after the operation or up to 1 year after a procedure that has involved the implantation of a foreign material (mesh, vascular graft, prosthetic joint, and so on). Incisional infections are the most common; they account for 60% to 80% of all SSIs and have a better prognosis than organ/space-related SSIs do, with the latter accounting for 93% of SSI-related mortalities.

Understanding the microbiology of SSIs is important to guide initial empirical therapy for infections in a specific patient, as well as for identification of outbreaks and selection of strategies for the management of prophylactic antibiotics.

Surgical site infections (SSIs) are a real risk associated with any surgical procedure and represent a significant burden in terms of patient morbidity and mortality, and cost to health services around the world. Surgical wound infection is a common postoperative complication and causes significant postoperative morbidity and mortality, prolongs hospital stay, and adds between 10% and 20% to hospital costs.

Surgical site infections are the 3rd most common post op infection in surgical patients after urinary tract and respiratory tract infections. Surgical site infections are usually secondary to inoculation of bacteria from patients own endoflora (eg. Anterior nares, mouth, rectum) and less often from the environment.

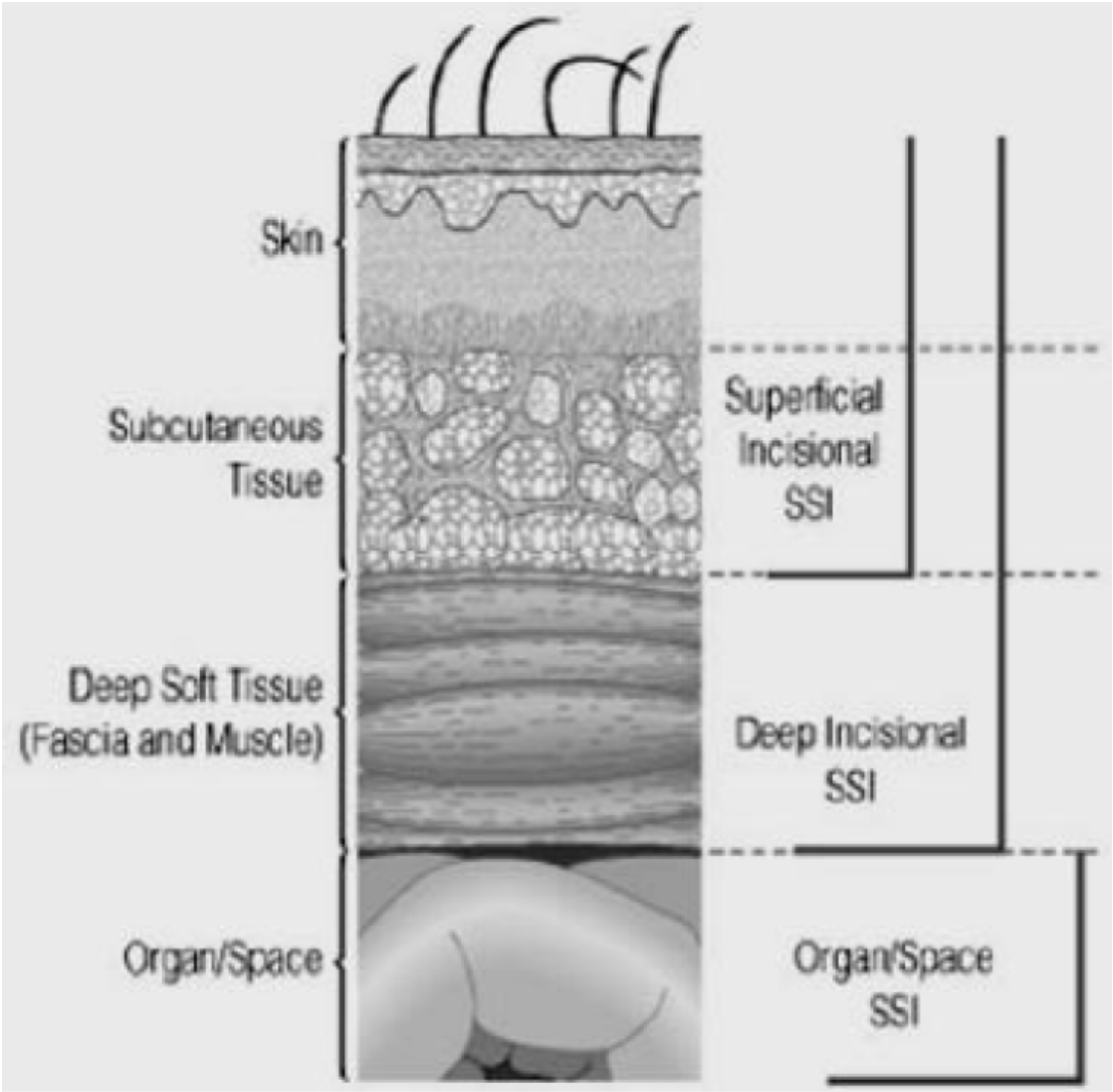
Definition of SSI

Any purulent discharge from a closed surgical incision, together with signs of inflammation of the surrounding tissue should be considered as wound infection, irrespective of whether micro-organisms can be cultured. Infection can occur at an incision site within 30 days of an operation, but if an implant is placed (eg. Arthroplasty, mesh) the definition is extended upto 1 year. There are intermediate categories of wounds that may or may not be infected—namely, wounds that have a small amount of clear discharge. These wounds maybe considered as 'possibly' or 'probably' infected. In 1992, the Surgical Wound Infection Task Force replaced the term 'surgical wound infection' with ‘surgical site infection', to include infections of organs or spaces deep in the

skin and soft tissues, such as peritoneum and bone. Surgical site infection is classified into superficial site infection and organ or space infection.

Types of SSI

- Superficial Incisional SSI
- Deep Incisional SSI
- Organ / Space SSI



CRITERIA FOR DEFINING A SURGICAL SITE INFECTION (SSI)

Superficial Incisional SSI

Infection occurs within 30 days after the operation *and* Infection involves only skin or subcutaneous tissue of the incision *and* at least *one* of the following:

1. Purulent drainage, with or without laboratory confirmation, from the superficial incision.

2. Organisms isolated from an aseptically obtained culture of fluid or tissue from the

superficial incision.

3. At least one of the following signs or symptoms of infection: pain or tenderness, localized swelling, redness, or heat *and* superficial incision is deliberately opened by surgeon, *unless* incision is culture-negative.

4. Diagnosis of superficial incisional SSI by the surgeon or attending physician.

Do *not* report the following conditions as SSI:

1. Stitch abscess (minimal inflammation and discharge confined to the points of suture penetration).

2. Infection of an episiotomy or newborn circumcision site.

3. Infected burn wound.

4. Incisional SSI that extends into the fascial and muscle layers (see deep incisional SSI).

Deep Incisional SSI

Infection occurs within 30 days after the operation if no implant† is left in place or within 1 year if implant is in place and the infection appears to be related to the operation *and* infection involves deep soft tissues (e.g., fascial and muscle layers) of the incision *and* at least *one* of the following:

1. Purulent drainage from the deep incision but not from the organ/space component of the surgical site.

2. A deep incision spontaneously dehisces or is deliberately opened by a surgeon when the patient has at least one of the following signs or symptoms: fever (>38ºC), localized pain, or tenderness, unless site is culture-negative.

3. An abscess or other evidence of infection involving the deep incision is found on direct examination, during reoperation, or by histopathologyic or radiologic examination.

4. Diagnosis of a deep incisional SSI by a surgeon or attending physician.

Notes:

1. Report infection that involves both superficial and deep incision sites as deep incisional SSI.

2. Report an organ/space SSI that drains through the incision as a deep incisional SSI.

Organ/Space SSI

Infection occurs within 30 days after the operation if no implant† is left in place or within 1 year if implant is in place and the infection appears to be

related to the operation *and* infection involves any part of the anatomy (e.g., organs or spaces), other than the incision, which was opened or manipulated during an operation *and* atleast *one* of the following:

1. Purulent drainage from a drain that is placed through a stab wound‡ into the organ/space.

2. Organisms isolated from an aseptically obtained culture of fluid or tissue in the organ/space.

3. An abscess or other evidence of infection involving the organ/space that is found on direct examination, during reoperation, or by histopathologic or radiologic examination.

4. Diagnosis of an organ/space SSI by a surgeon or attending physician. National Nosocomial Infection Surveillance definition: a nonhuman-derived implantable foreign body (e.g., prosthetic heart valve, nonhuman vascular graft, mechanical heart, or hip prosthesis) that is permanently placed in a patient during surgery. If the area around a stab wound becomes infected, it is not an SSI. It is considered a skin or soft tissue infection, depending on its depth.

CDC Classification of Surgical Wounds

Classification	Criteria
Clean	Elective, not emergency, non-traumatic, primarily closed; no acute inflammation; no break in technique; respiratory, gastrointestinal, biliary and genitourinary tracts not entered
Clean-contaminated	Urgent or emergency case that is otherwise clean; elective opening of respiratory, gastrointestinal, biliary or genitourinary tract with minimal spillage (e.g. appendectomy) not encountering infected urine or bile; minor technique break.
Contaminated	Non-purulent inflammation; gross spillage from gastrointestinal tract; entry into biliary or genitourinary tract in the presence of infected bile or urine; major break in technique; penetrating trauma <4 hours old; chronic open wounds to be grafted or covered
Dirty	Purulent inflammation (e.g. abscess); preoperative perforation of respiratory, gastrointestinal, biliary or genitourinary tract; penetrating trauma >4 hours old

Antibiotic prophylaxis

Inoculation of the surgical site occurs during surgery, either inward from the skin or outward from the internal organ being operated on, hence the rationale for skin preparation with antiseptics, and prophylactic administration of antibiotics. The microbiology of SSI depends on the type of operation being performed, but most SSIs are caused by skin-derived gram-positive cocci,

including *Staphylococcus aureus*, coagulase-negative staphylococci (usually *Staphylococcus epidermidis*), and *Enterococcus spp*. With surgery of the head and neck, (when pharyngoesophageal structures are entered) or intestinal surgery, enteric aerobic (e.g. *Escherichia coli*) and anaerobic (e.g. *Bacteroides fragilis*) bacteria may cause SSIs. However, it is only the surgical incision that is afforded protection, and antibiotics are not a panacea. If not administered properly, antibiotic prophylaxis will not be effective and may be harmful. Antibiotic prophylaxis is indicated clearly for most clean-contaminated and contaminated (or potentially contaminated) operations. Antibiotic prophylaxis of clean surgery is controversial. Where bone is incised (e.g. craniotomy or sternotomy) or a prosthesis is inserted, antibiotic prophylaxis is generally indicated. The choice of antibiotic should be guided by four principles: safety, narrow spectrum coverage of relevant pathogens, no general use for treatment of infection, and short-duration administration (ideally, a single dose given one to two hours before surgery; certainly for no more than 24 hours (48 hours for cardiac surgery). A first-generation cephalosporin is the preferred agent for most patients, with clindamycin preferred for patients with a history of anaphylaxis to penicillin. Unfortunately, recent US data indicate that prophylactic antibiotics are administered to only 56% of patients within one hour of surgery. Disconcertingly, antimicrobial prophylaxis was discontinued within 24 hours of surgery only 41% of the time. Prolongation of antibiotic prophylaxis beyond 24 hours not only provides no benefit, but can be associated with complications, including *Clostridium difficile*-associated

colitis, nosocomial infections other than SSI, and the emergence of multi-drug-resistant pathogens. Both pneumonia and catheter-related infections have been associated with prolonged antibiotic prophylaxis, as has the emergence of SSI caused by methicillin-resistant *Staphylococcus aureus*

Timing of antibiotic prophylaxis:

A prospective observational study using logistic regression to analyse data collected from patients undergoing elective clean or clean-contaminated surgery at a teaching hospital examined the timing of antibiotic prophylaxis administration as a risk factor for SSI.(60)

Patients were assigned to groups according to the time between their first dose of antibiotic prophylaxis and the initial surgical incision. The early group received prophylaxis 2–24 hours pre-incision, the preoperative group 0–2 hours pre-incision, the perioperative group up to 3 hours post-incision and the postoperative group received antibiotic prophylaxis 3–24 hours post-incision. Forty-four of 2847 included patients (1.5%) developed SSI. Logistic regression demonstrated that there were statistically significantly more infections in the early and postoperative groups compared with the perioperative group .Results were further stratified according to the hour that prophylaxis was administered in relation to the time of surgery – the early group were excluded from this analysis. The lowest SSI rate occurred in patients receiving antibiotic prophylaxis 0–2 hours prior to surgery. A statistically significant trend was observed toward higher rates of infection with each successive hour. That

antibiotic administration was delayed after the surgical incision (*z* score = 2.00, *P* <0.05 Wilcoxon test).

Evidence statement – timing of antibiotic prophylaxis

There is evidence that administration of antibiotic prophylaxis up to 2 hours preoperatively is associated with the lowest rates of infection in clean and clean contaminated surgery.

Recommendations on antibiotic prophylaxis

Give antibiotic prophylaxis to patients before:

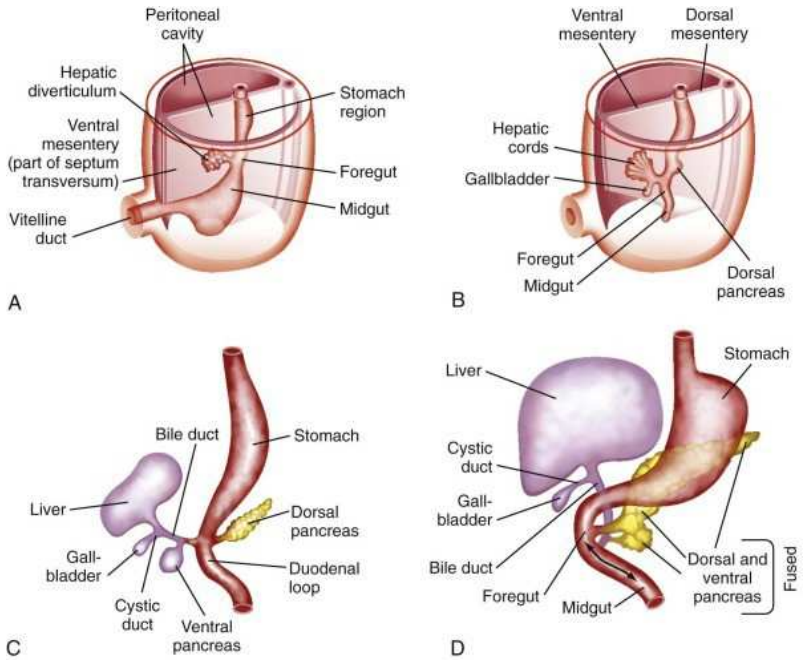
- clean surgery involving the placement of a prosthesis or implant
- clean-contaminated surgery
- contaminated surgery.

Do not use antibiotic prophylaxis routinely for clean non-prosthetic uncomplicated surgery. Use the local antibiotic formulary and always consider potential adverse effects when choosing specific antibiotics for prophylaxis. Consider giving a single dose of antibiotic prophylaxis intravenously on starting anaesthesia. However, give prophylaxis earlier for operations in which a tourniquet is used. Before giving antibiotic prophylaxis, consider the timing and pharmacokinetics (for example, the serum half-life) and necessary infusion time of the antibiotic. Give a repeat dose of antibiotic prophylaxis when the operation is longer than the half-life of the antibiotic given. Give antibiotic treatment (in addition to prophylaxis) to patients having surgery on a dirty or infected wound. Inform patients before the operation, whenever possible, if

they will need antibiotic prophylaxis, and afterwards if they have been given antibiotics during their operation.

EMBRYOLOGY

Liver arises in the fourth week as a diverticulum from the ventral surface of the duodenal foregut, close to its junction with the midgut where the later is continuous with the yolk stalk this diverticulum, lined with endoderm, grows vertically and cranially into the septum transversum, its tip diverges into two solid hepatic buds of cells, the further right and left lobes of liver, the buds develops into epithelial trabeculae or sheet (so called hepatic cylinders), which branch and anastamose to form a closed meshwork. The interval of meshwork become filled with blood sinusoids and on section the organ has the appearance of vascular sponge, The original diverticulum from the duodenum forms the bile duct and from its distal part the cystic duct and gall bladder arise as an outgrowth, solid at first but latercanalized.



ANATOMY

The **gallbladder** is a pear-shaped sac lying on the visceral surface of the right lobe of the liver in a fossa between the right and quadrate lobes.

It has:

- a rounded end (**fundus of gallbladder**), which may project from the inferior border of theliver,
- a major part in the fossa **(body of gallbladder**), which may be against the transverse colon and the superior part of theduodenum;
- anarrowpart(**neckofgallbladder**)withmucosalfoldsformingthespiralfold.

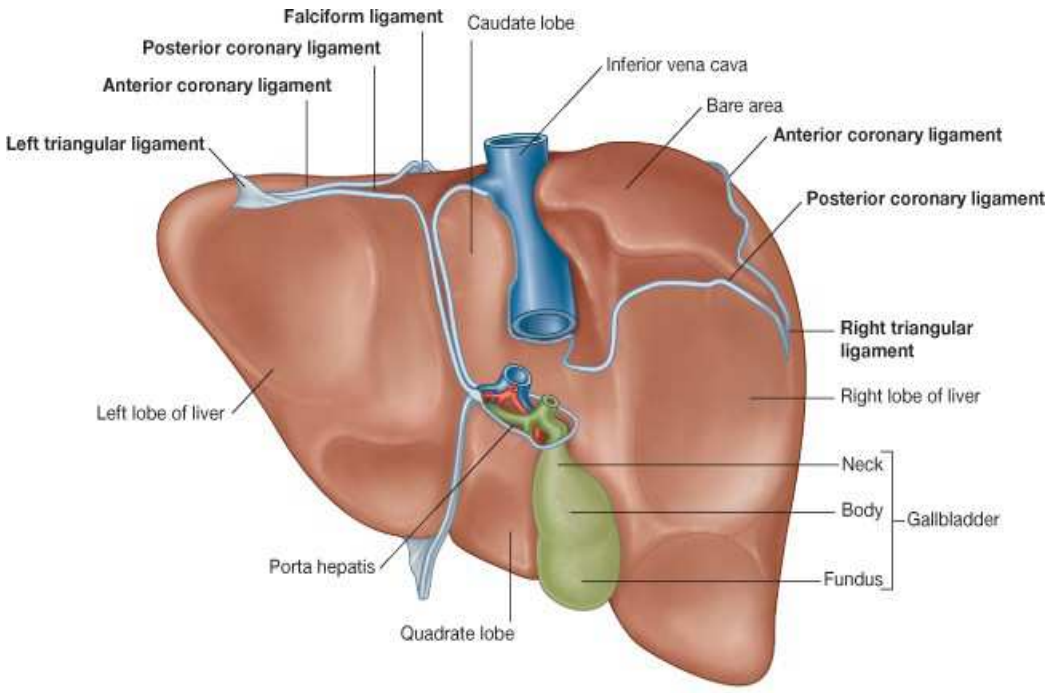


Figure 2: Anatomy of the gall bladder

The gallbladder varies from 7 to 10 cm in length and from 2.5 to 3.5 cm in width. A moderately distended gallbladder has a capacity of 50 to 60 ml of bile.

Hartmann's pouch is an asymmetrical bulge of the infundibulum that lies close to the gallbladder's neck. It is a common site for a gallstone to lodge. The neck points in a cephalad and dorsal direction to join the cysticduct.

The gallbladder wall consists of five layers. The innermost layer is the epithelium, and the other layers are the lamina propria, smooth muscle, perimuscular subserosal connective tissue, and serosa. The gallbladder has no muscularis mucosa or submucosa. The lamina propria contains nerve fibers, vessels, lymphatics, elastic fibers, loose connective tissue, and occasional mast cells and macrophages. The muscle layer is a loose arrangement of circular, longitudinal, and oblique fibers without well-developed layers.

Rokitansky-Aschoff sinuses are invaginations of epithelium into the lamina propria, muscle, and subserosal connective tissue. The ducts of Luschka are tiny bile ducts found around the muscle layer on the hepatic side of the gallbladder. [12]

Anatomy of biliary tract

The *right and left hepatic ducts* emerge from the liver and unite in the porta hepatis to form the *common hepatic duct.* The cystic duct arises from the gallbladder and joins the common hepatic duct to form the common bile duct. The length of the cystic duct is variable, averaging between 2 and 4 cm. The

cystic duct contains a variable number of mucosal folds, similar to those found in the neck of the gallbladder. Although referred to as valves of Heister, these spiral folds do not have a valvular function.

The *common bile duct* runs between the layers of the lesser omentum, lying anterior to the portal vein and to the right of the hepatic artery. Passing behind the first part of the duodenum in a groove on the back of the head of the pancreas, it enters the second part of the duodenum. The duct runs obliquely through the posterior-medial wall, usually joining the main pancreatic duct to form the *Ampulla of Vater (1720).* The ampulla makes the mucous membrane bulge inwards to form an eminence: the *duodenal papilla*. In about 10-15% of subjects the bile and pancreatic ducts open separately into theduodenum.

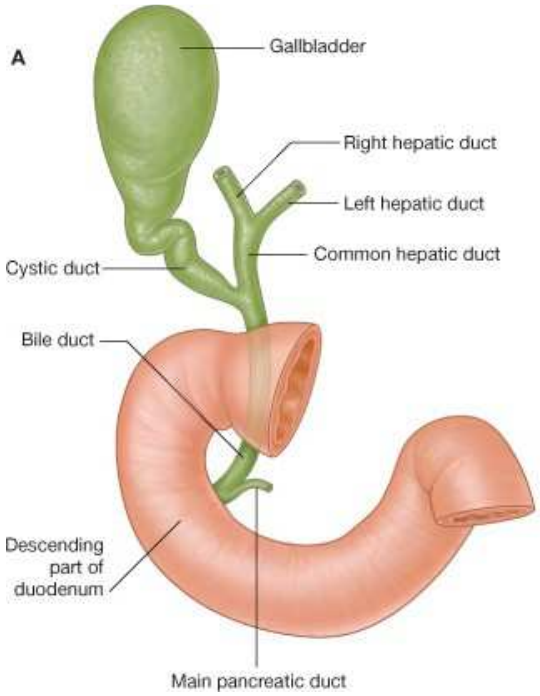


Figure 3: Anatomy of the biliary tree

The dimensions of the common bile duct depend on the technique used. At operation it is about 0.5-1.5 cm in diameter. Using endoscopic cholangiography, it is usually less than 11 mm and values greater than 18 mm are pathological. By ultrasound the values are less, the common bile duct being 2-5 mm and values greater than this are abnormal.[13]

The duodenal portion of the common bile duct is surrounded by a thickening of both longitudinal and circular muscle fibres derived from the intestine. This is called the sphincter of Oddi. [14]

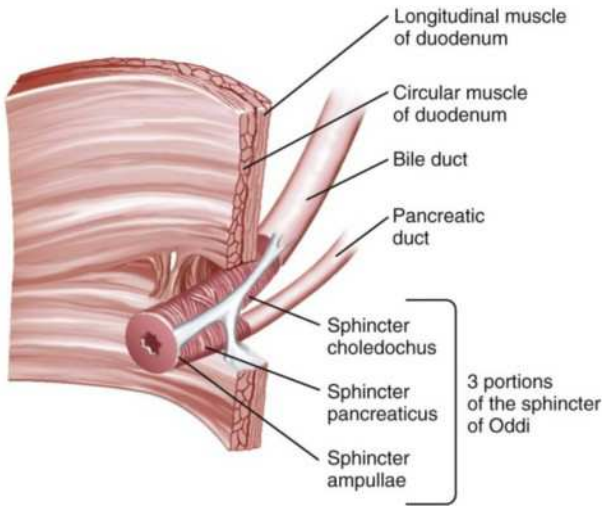


Figure 4: Anatomy of the sphincter of Oddi

Calot's Triangle

In 1891, Calot described a triangular anatomic region formed by the common hepatic duct medially, the cystic duct laterally, and the cystic artery superiorly. Calot's triangle is considered by most to comprise the triangular area with an upper boundary formed by the inferior margin of the right lobe of the liver, rather than the cystic artery. During performance of a cholecystectomy, clear visualization of the hepatocystic triangle is essential

with accurate identification of all structures within this triangle.[12]

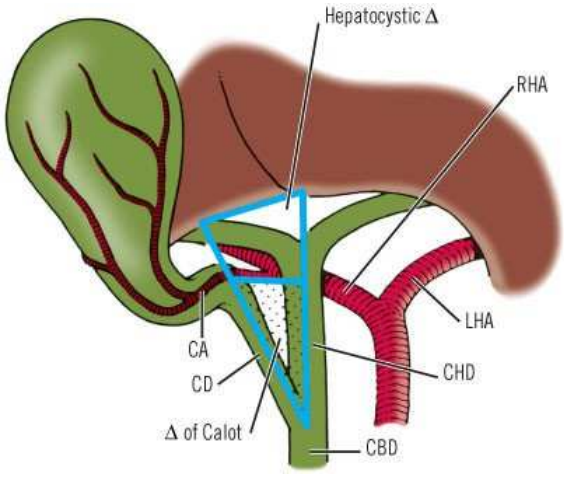


Figure 5: Calot's triangle

Blood supply

The gallbladder receives blood from the *cystic artery.* This branch of the hepatic artery is large, tortuous and variable in its anatomical relationships. Smaller blood vessels enter from the liver through the gallbladder fossa. The venous drainage is into the *cystic vein* and hence into the portal venous system.

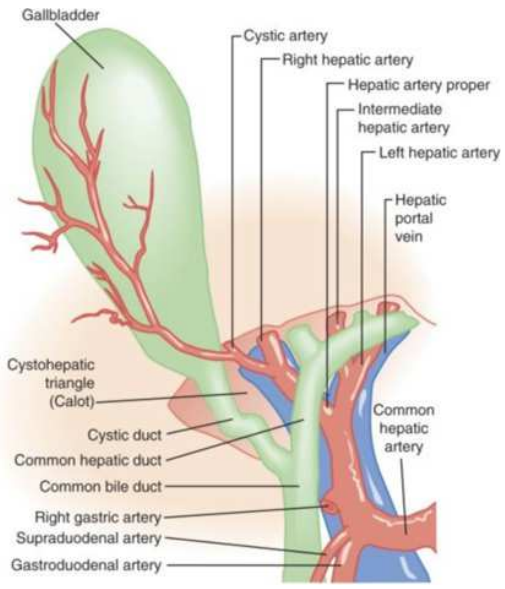


Figure 6: Arterial blood supply of the gall bladder

The arterial blood supply to the supra-duodenal bile duct is generally by two main (axial) vessels, which run beside the bile duct in the 3'o' clock and 9'o' clock position. [15] These are supplied predominantly by the retro-duodenal artery from below, and the right hepatic artery from above, although many other vessels contribute. This pattern of arterial supply would explain why vascular damage results in bile duct stricturing.

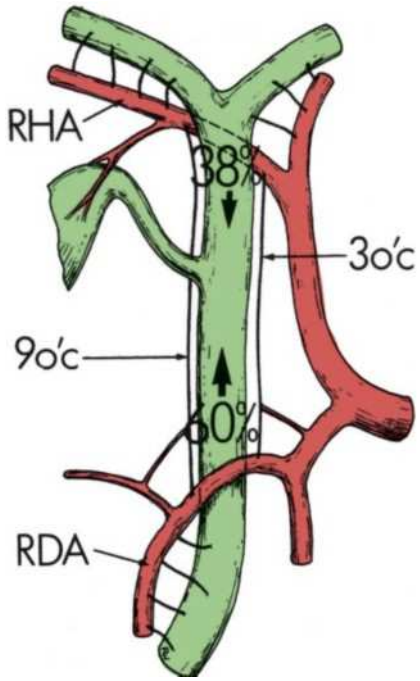


Figure 7 : Arterial blood supply of the extrahepatic biliary tree

Lymphatics

There are many lymphatic vessels in the sub mucous and sub peritoneal layers. These drain through the cystic gland at the neck of the gallbladder to glands along the common bile duct, where they anastomose with lymphatic from the head of the pancreas.

Nerve supply

The gallbladder and bile ducts are liberally supplied with nerves, from both the parasympathetic and sympathetic system. [16]

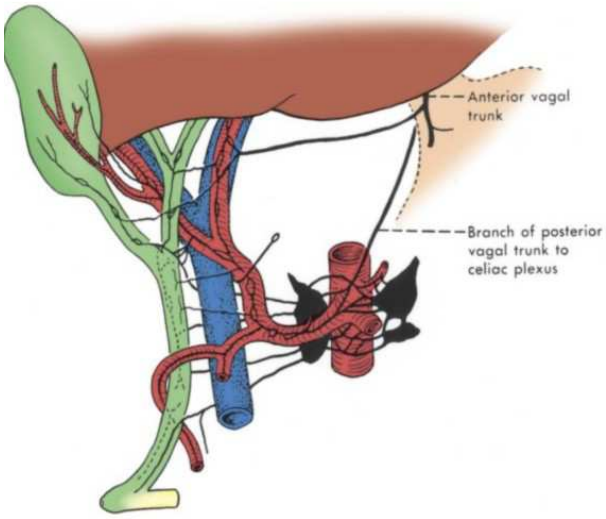


Figure 8: Nerve supply to the extrahepatic bile tree.

Laparoscopic anatomy [17]

The advent and popularity of LC has led to a new look and insights into the biliary anatomy especially of the Calot's triangle area and the term "laparoscopic anatomy" has actually found a place even in anatomy texts.

The different anatomical 'laparoscopic view' of the area around the gallbladder especially the Calot's triangle does contribute to misidentification of strictures. The method of retraction during the laparoscopic procedure tends to distort the Calot's triangle by actually flattening it rather than opening it out. Also the reluctance to (or difficulty) performing a fundus first cholecystectomy during the laparoscopic procedure as approved to open procedure also contributes to the some lack of exposure of the Calot'striangle.

Finally the ‘posterior’ or ‘reverse’ dissection of the Calot’s triangle, which is popular during LC, again gives a different view of the area and since the gallbladder is view of the area and since gallbladder is flipped over during the method may lead to further anatomical distortion. The Rouviere’s sulcus is fissure on the liver between the right lobe and caudate process and is clearly seen during a LC during a posterior dissection in majority of patients.

It corresponds to the level of the porta hepatic where the right pedicle enters the liver. It has been recommended that all dissection be kept to a level above (or anterior) to this sulcus to avoid injury to the bileduct.

Also, this being an “extrabiliary” reference point it does not get affected by distortion due to pathology. Similarly, a clear delineation of the junction of cystic duct with the gallbladder along with the demonstration of a space between the gallbladder and the liver clear of any structure other than the cystic artery (safety window or critical window) is also recommended as an essential step to prevent bile duct injury.

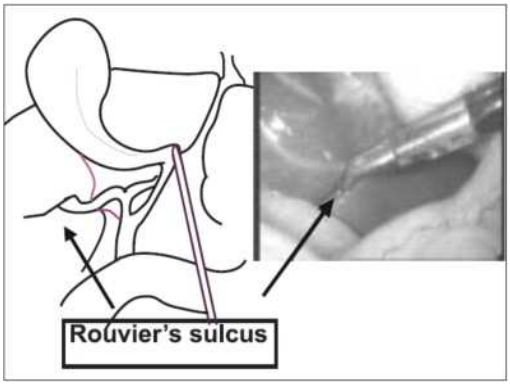


Figure 9: Rouviere’s sulcus

GALLSTONES

INCIDENCE:

Gallstones are the most common biliary pathology. The incidence of biliary calculous disease varies widely throughout the world. By the age of 75, about 35% of women and 20% of men would have developed gallstones. The incidence of gallstone disease in Asia is considerable and constitutes a problem of enormous magnitude. The incidence of cholesterol gallstones is increasing in Asia for the reasons that may be related to environmental and dietary considerations.

Most patients with gallstones are asymptomatic and only about 10% will have developed symptoms five years after discovery. In a functioning gall bladder, most of the gall stones are cholesterol stones. Gall stone disease is a relatively common problem in our country particularly in North India. It is estimated that more than sixty percent of these patients have cholesterol stones. Recent studies from south India have highlighted pigment and mixed variety of gall stones to be more common (> 90 %) in contrast to cholesterol stones.

RISK FACTOR ASSOCIATED WITH GALLSTONE FORMATION:[20]

1.Cholesterolstones

Age > 40years

i.Estrogens

a. Female sex (2-3 times the risk inmen)

b. Pregnancy (risk increases with number ofpregnancies)

c. Estrogen containingOCPs.

ii. Genetic or ethnicvariation

iii. High fat, low fiberdiet

iv. Obesity

v. Hyperlipidaemia

vi. Bile salt loss (Ileal disease or resection; Crohn's disease)

vii. Cysticfibrosis

viii. Anti-hyperlipidaemic drugs (Clofibrate)

ix. Impaired gall bladderemptying

a. Truncalvagotomy

b. Type-1diabetes

c. Octreotide

d. Total parenteralnutrition

e. Starvation or rapid voluntary weightloss

2. Pigmentstones

i. Haemolyticdisease

ii. Biliarystasis

iii. Biliaryinfection

In India, there is a dual pattern of prevalence. Some studies have shown that North Indians are more prone to cholelithiasis than South Indians. The nature of the disease is also different in North India and South India. In North

India, Cholesterol stones form the majority of gallstones. In contrast to this, pigment stones are more frequent in South India.

CLINICAL FEATURES:

Clinical Presentation of Gallstones:

1. Asymptomatic.
2. Biliarycolic.

i. Right subcostal or epigastric pain radiating to back or lower pole ofscapula lasting for 20 minutes to 6hours.

ii. Associated with vomiting, brought on by (any)food.

iii. May disturb sleep.

3. Flatulent dyspepsia.
4. Acute Cholecystitis - Calculous (as opposed to Acalculous)/ Empyema gallbladder/ Gangrenous Gallbladder.

i. Severe pain and tenderness in right subcostal region - Murphy sign - pain on palpation of the right upper quadrant when the patient inhales.

ii. Fever and leucocytosis.

5. Chronic calculous Cholecystitis - repeated episodes of right hypochondrial pain with/without fever and vomiting.

6. Cholangitis - Fever with chills/rigors, transient jaundice, upper abdominal pain, vomiting - Charcot triad (right upper quadrant pain, fever, and jaundice)

7. Mucocele - Heaviness in upper abdomen; palpable lump.
8. Choledocholithiasis with extra-hepatic cholestasis.
9. Biliary pancreatitis.
10. Gallstone ileus.
11. Gallbladder perforation.
12. Gallbladder carcinoma.

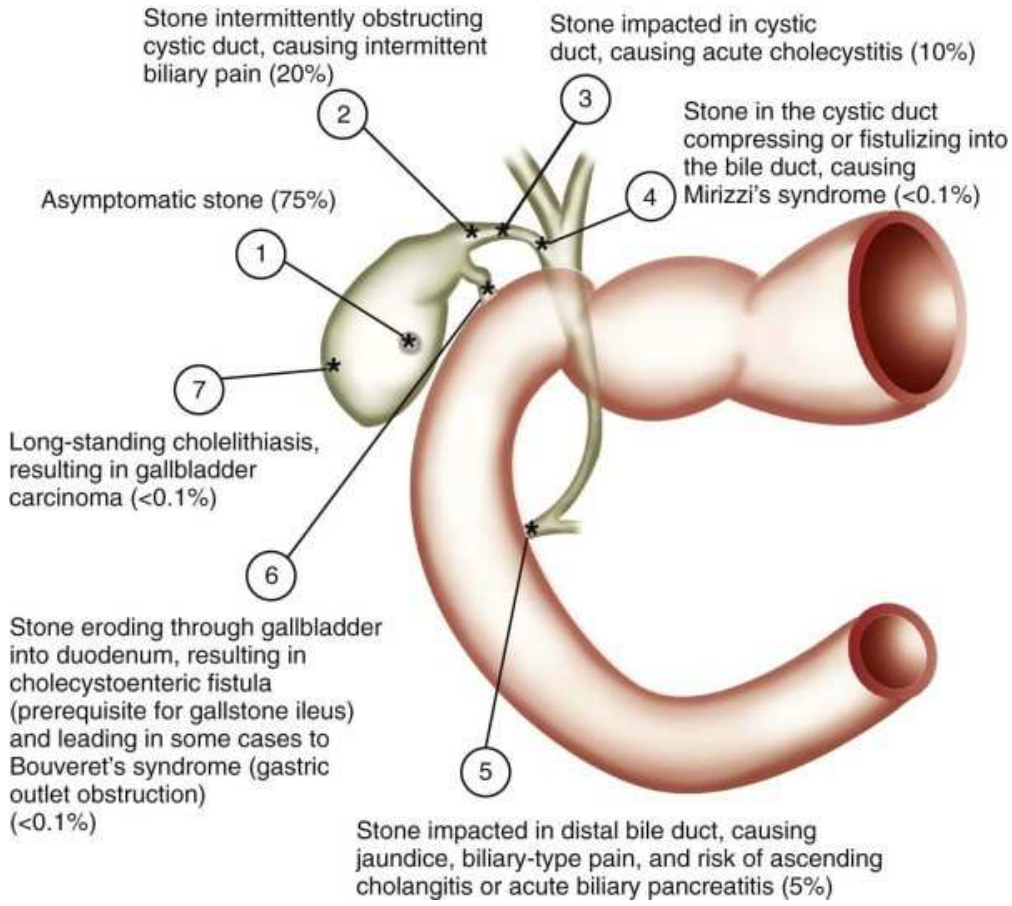


Figure 16: Schematic depiction of the natural history and complications of gallstones.

The percentages indicate the approximate frequencies of complications that occur in untreated patients, based on natural history data. The most frequent outcome is for the patient with a stone to remain asymptomatic throughout life (1). Biliary pain (2), acute cholecystitis (3), cholangitis (5), and pancreatitis (5) are the most common complications. Mirizzi's syndrome (4), cholecystoenteric fistula (6), Bouveret's syndrome (6), and gallbladder cancer (7) are relatively rare.[22]

INVESTIGATIONS:

A variety of diagnostic modalities are available for the patient with suspected disease of the gallbladder and the bile ducts. In 1924, the diagnosis of gallstones was improved significantly by the introduction of oral cholecystography by Graham and Cole. For decades it was the mainstay of investigation for gallstones. In the 1950's biliary scintigraphy was developed, and later trans hepatic and endoscopic retrograde cholangiography, allowing imaging of the biliary tract. Later ultrasonography, computed tomography (CT), and magnetic resonance imaging (MRI), vastly improved the ability to image the biliary tract.[24]

1. Blood investigations.
2. Plain X-ray abdomen.
3. Oral Cholecystography.
4. Cholangiography.
4. Ultrasonography(USG).
5. Computed Tomography(CT).

6. Magnetic Resonance Cholangio Pancreatography(MRCP).
7. Endoscopic Retrograde Cholangio Pancreatography(ERCP).
8. Hepato biliary Scintigraphy.

Blood investigations:

Nearly 50% of patients with symptomatic gallstone disease will have abnormal transaminases. An elevated white blood cell count alerts the clinician to the possibility of acute cholecystitis, a condition requiring more urgent treatment. Serum lipase and amylase levels are helpful in cases of diagnostic uncertainty or suspected concurrent pancreatitis. Coagulation parameter results measured by prothrombin (PT) and activated partial thromboplastin time (aPTT) might be abnormal in the severely jaundiced patient due to dysfunction in vitamin K absorption.

Plain X-ray abdomen:

PlainabdominalX-rayisapreliminaryscreeningtestsinceonlyabout10%of gallstones are radio-opaque. A porcelain gallbladder (heavily calcified) should be removed surgically because of increased risk of gallbladder cancer. More the less, gallstones are so common that they are the most frequent cause of discrete right upper quadrant calcifications. The smaller numbers of calcified gallstones that will be seen on plain films are indicative that the majority of stones are cholesterol based and contain little calcium.

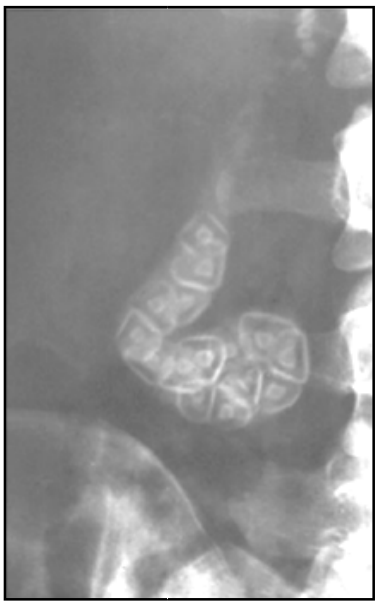
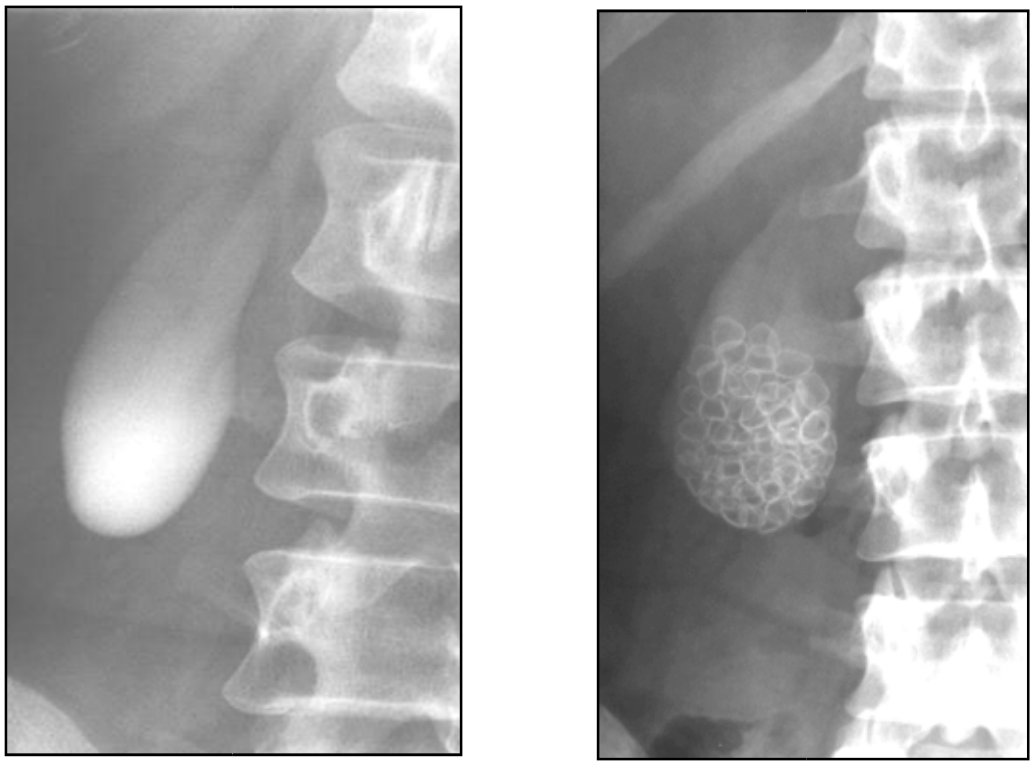


Figure 17A: Plain radiograph showing radio-opaque stones in the gallbladder

Figure 17B: Porcelain gall bladder

Oral Cholecystography:

In 1924, Graham and Cole introduced the concept of oral cholecystography. For many years, this test was considered the main stay and gold standard for the diagnosis of gall stone disease. It was based on two physiologic principles; halogenated dyes are excreted in bile and the gallbladder is capable of concentrating bile 8 to 10 fold. In a normally functioning gall bladder, dye is concentrated as are sult or the absorptive function of the gallbladder and it will appear opacified. The presence of gallstones is suggested by the appearance of filling defects in an otherwise opacified gallbladder or by non-visualization. The latter is indicative of reduced absorption, which is consistent with chronic cholecystitis. The accuracy of oral cholecystography is between 95 - 99%.



Normal Oral cholecystogram

Cholecystogram showing multiple gallstones

Figure 18: Oral cholecystography

Cholangiography:

Routine cholangiography during laparoscopic cholecystectomy has been advocated to confirm anatomy and thus prevent ductal injury.

An intra operative cholangiography provides a “road map” of entire biliary system and aids in the dissection of the function between cystic and common bileducts which is of great value in cases where anatomic land marks are not clearly identified or where variation to the normal ductal anatomy are present.

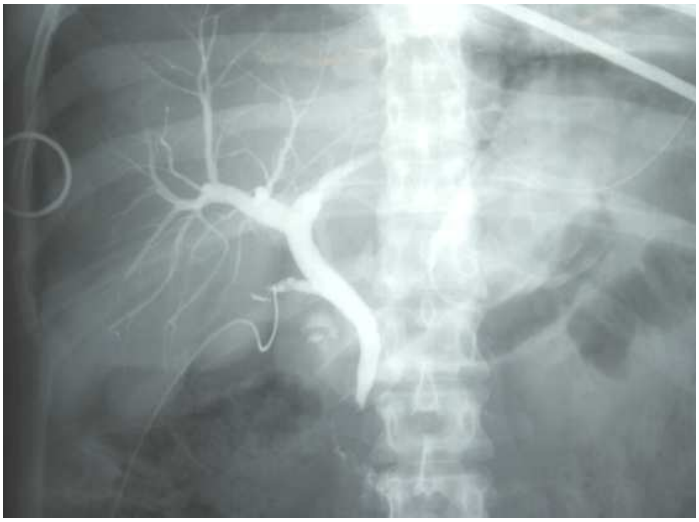


Figure 19: Normal intraoperative cholangiogram. Contrast can be seen clearly entering the cystic duct, flowing into the common bile duct and up into the hepatic ducts

Ultrasonography:

An ultrasound is the initial investigation of any patient suspected of disease of the biliary tree. It is non-invasive, painless, does not submit the patient to radiation, and can be performed.

Ultrasonography can detect stones larger than 1 to 2 mm in diameter; can rule out alternative causes of right upper quadrant pain, such as tumor or abscess; and can suggest the presence of common bile duct stones by showing bile duct dilatation.

Findings include gallstones or sludge and one or more of the following conditions:

1. Gallbladder wall thickening (>2-4 mm) - False positive wall thickening found in acute hepatitis, portal hypertension, hypo albuminemia, ascites, congestive cardiac failure and carcinoma.[26]
2. Gallbladder distention (diameter >4 cm, length >10 cm).
3. Pericholecystic fluid from perforation or exudates.
4. Air in the gallbladder wall (indicating gangrenous cholecystitis or emphysematous cholecystitis).

The diagnosis of stones by ultrasound examination is highly specific if the operator sees a moveable echogenic spot that produces a shadow. Stones are acoustically dense and reflect the ultrasound waves back to the ultrasonic transducer. Because stones block the passage of sound waves to the region behind them, they also produce an acoustic shadow. Ultrasound examination sludge as a lower, liquid phase with tiny echoes that do not produce shadow.

Its disadvantage is that it is operator-dependent, number of stones may be underestimated.

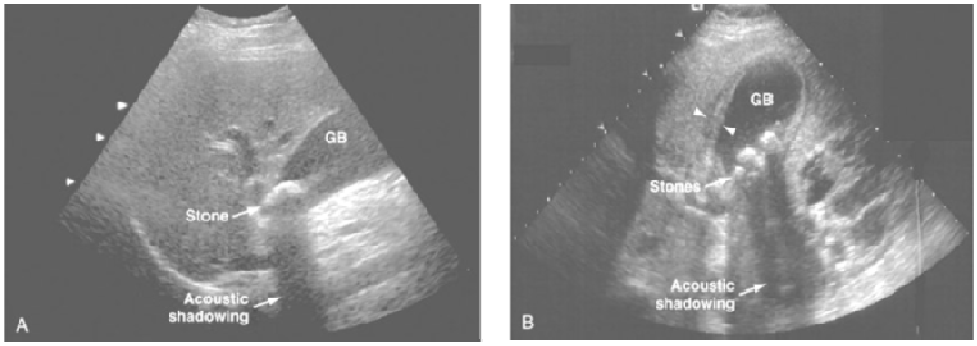


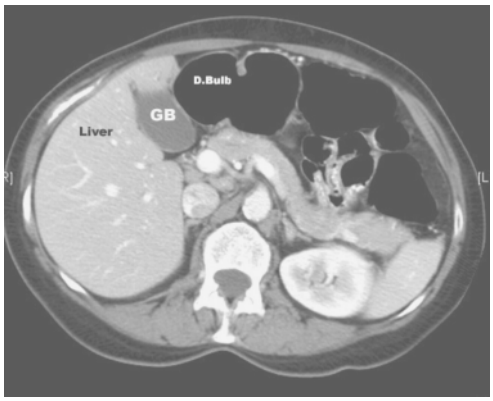
Figure 20(A): Typical ultrasonographic appearance of cholelithiasis. A gallstone is present within the lumen of the gallbladder (GB), casting an acoustic shadow.

Figure 20(B): Cholelithiasis in the setting of acute cholecystitis. Multiple gallstones can be seen within the gallbladder lumen with associated acoustic shadowing. In addition, the gallbladder wall is thickened (arrowheads).

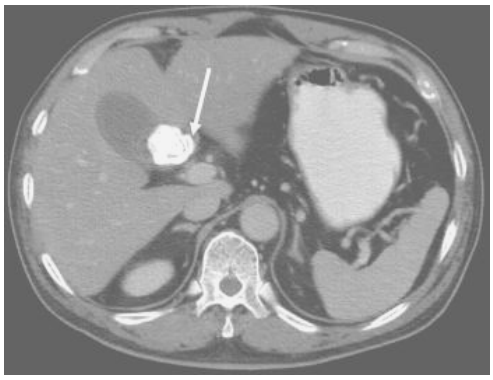
Computed Tomography:

Computed tomography scan are not a first-line test for the diagnosis of cholelithiasis. Obvious gallstones frequently are missed by routine CT, although they may be seen as incidental finding, if they are densely calcified. Although this test is not particularly sensitive for identifying gallstones, it does not provide important information regarding the nature, extent, and the location of biliary dilatation and masses in and around the biliary tract and for pancreas. In general, this test provides more useful information than ultrasonography when the concern is extrahepatic obstruction owing to

cause other than choldocholithiasis. Limiting factors for CT scanning include patient exposure to ionizing radiation and cost.



Normal CT Scan of gall bladder



CT image demonstrates a large gallstone (arrow) in the gallbladder.

Figure 21: CT image of gall bladder

Magnetic Resonance Cholangio Pancreatography (MRCP):

Recently, MR cholangio-pancreatography (MRCP) has emerged as an alternative to endoscopic retrograde cholangiography, averting the need for invasive diagnostic testing in patients who are unlikely to require any therapeutic intervention. With MRCP, no contrast material is administered,

but native high signal intensity of fluid on T2-weighted images permits imaging of the biliary tree. A preliminary study has found that the sensitivity of MRI cholangiography for detecting choledocholithiasis is over 90 %. [27]

Figure 22: Normal MRCP image

Endoscopic Retrograde Cholangio Pancreatography (ERCP): [28]

Using a side-viewing endoscope, the common bile duct can be cannulated and a cholangiogram performed using fluoroscopy. The procedure requires intravenous sedation for the patient. The advantages of endoscopic retrograde cholangiography (ERC) include direct visualization of the ampullary region and direct access to the distal common bile duct, with the possibility of therapeutic intervention. The test is rarely needed for uncomplicated gallstone disease, but for stones in the common bile duct, in particular when associated with obstructive jaundice, cholangitis, or gall stone pancreatitis, ERCP is the diagnostic and often therapeutic procedure of choice. Once the endoscopic cholangiogram has shown ductal stones,

sphincterotomy and stone extraction can be performed, and the common bile duct cleared of stones.

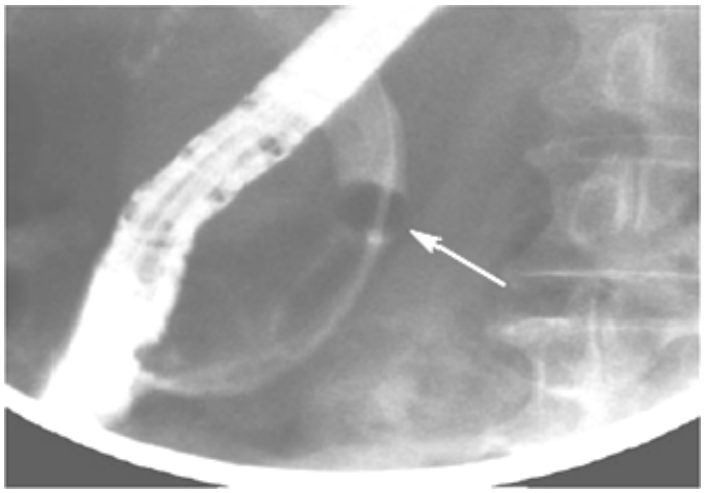


Figure 23: Endoscopic Retrograde cholangiopancreatography demonstrating stone obstructing the common bile duct (arrow).

Hepatobiliary Scintigraphy:

Nuclear cholescintigraphy permits the rapid assessment of gallbladder function in a patient with suspected acute cholecystitis.[29] The short-lived isotope technetium- 99m is bound to one of several iminodiacetic acids (such as hydoxyiminodiacetic acid- HIDA or diisopropyl iminodiacetic acid - DISIDA) that are excreted into the bile ducts. Gamma rays emitted by the tracer are used to make an image of the bile ducts and gallbladder. Failure of the tracer to enter the gallbladder suggests obstruction of the neck of the gallbladder, as occurs in acute cholecystitis.

HIDA scan is the most sensitive and specific test for acute cholecystitis - calculus and acalculous. A poorly contracting gallbladder (biliary dyskinesia) might cause the patient's symptoms, and HIDA scan helps in making the diagnosis. Cholescintigraphy can provide functional information about gallbladder contraction and can detect total obstruction of the bile duct, but it cannot provide anatomical information and cannot identify gallstones.

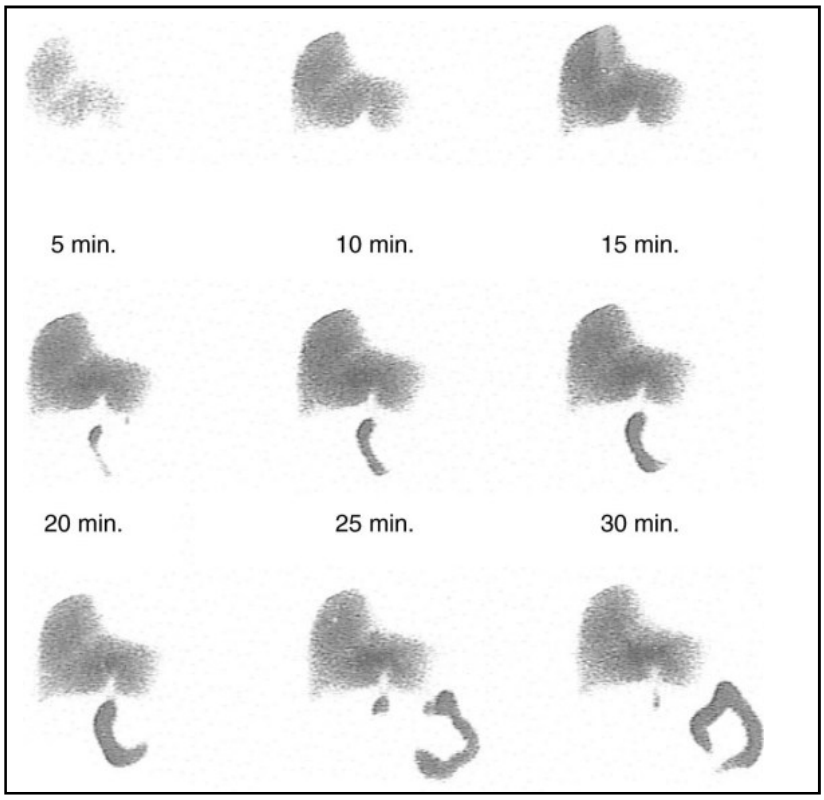


Figure 24: Cholescintigraphy demonstrating an obstructed cystic duct characteristic of acute cholecystitis.

The failure of the gallbladder to be visualized as a hot spot within 30 to 60 minutes constitutes a positive result and implies obstruction of the cystic duct.

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MANAGEMENT OF GALLSTONE DISEASES

NON-OPERATIVE MANAGEMENT [30]

Medical treatment of gallstone disease was first proposed by Schiff in Italy in 1873. Dabney of Virginia first reported the effective treatment of gallstones with bile acids in 1876.Despite these initial reports, the use of medical dissolution treatment did not gain acceptance until large clinical series were reported in the 1970s.

Contact dissolution of gallstones with solvents and percutaneous cholecystolithotomy techniques also have been reported, but these modalities have not proved superior to oral dissolution, shock-wave lithotripsy, or laparoscopic cholecystectomy and have been abandoned. The mainstay of current non-surgical treatment of gallstone disease is oral dissolution with ursodeoxycholic acid, with or without extracorporeal shock-wave lithotripsy.

1. DissolutionTherapy

The rationale for oral dissolution therapy is the reversal of the condition that led to formation of cholesterol gallstones, namely, the supersaturation of bile with cholesterol. Cholesterol stones dissolve if the surrounding medium is capable of solubilizing the cholesterol in the stones. Both *chenodeoxycholic acid* and *ursodeoxycholic acid* dissolve gallstones by decreasing biliary cholesterol secretion and desaturating bile. These agents encourage the removal of cholesterol from stones via micellar solubilization, formation of a liquid crystalline phase, or both.

Chenodeoxycholic acid was the first bile acid used for gallstone dissolution but has been abandoned because of side effects, including diarrhea and increased serum aminotransferase and cholesterol levels. Ursodeoxycholic acid is well tolerated and is currently used in oral dissolution regimens. Oral dissolution therapy should be considered for patients with uncomplicated gallstone disease, including those with mild, infrequent biliary pain. In addition, the gallbladder must function and the cystic duct must be patent to allow unsaturated bile and stones to clear from the gallbladder. Oral dissolution therapy works only on cholesterolstones.

Table 3: Selection Criteria for Oral Bile Acid DissolutionTherapy

Stage disease Of gallstone	• Symptomatic (biliary pain) without complications
Gallbladder function	• Opacification of gallbladder on oral cholecystography (patent cystic duct) • Normal result of stimulated cholescintigraphy (normal GBemptying) • Normal result of functional ultrasonography(normal gallbladder emptying after a test meal)

Stone characteristics	• Radiolucent on radiography • Isodense or hypodense to bile and absence of calcification on CT scan • Diameter <6 mm (optimal) or 6-10 mm(acceptable)

Ursodeoxycholic acid (ursodiol) is the preferred drug for oral dissolution treatment. It is taken in a dose of 10 to 15 mg/kg of body weight per day. Nighttime dosing is more effective and is associated with better patient compliance than mealtime dosing. Treatment should continue until stone dissolution is documented by two consecutive negative ultrasonograms at least one month apart.

2. Extracorporeal shock wave lithotripsy(ESWL)

The application of extra corporeal shock-wave lithotripsy to the treatment of gallstones was first applied to patients by Sauerbruch in 1985.The rationale for shock- wave lithotripsy is to diminish the surface-to-volume ratio of a stone, thereby increasing the efficacy of oral dissolution and decreasing stone size to allow small stones and debris to pass directly from the gallbladder into the intestine without causing symptoms. The technique involves the delivery of focused high-pressure sound waves to gallstones. Passage of the shock wave through the anterior and posterior walls of the stone liberates compressive and tensile forces and causes cavitation at the anterior surface of the stone, thereby leading to stone fragmentation. Factors that influence fragmentation include

the size, microcrystalline structure, and architecture of the stone.

Because shock-wave lithotripsy is usually combined with oral dissolution therapy, patient selection criteria for shock-wave lithotripsy are similar to those for oral dissolution treatment. Gallbladder function and cystic duct patency are required and are demonstrated by oral cholecystography, functional ultrasonography, or stimulated cholescintigraphy. Lithotripsy should be considered only for patients with mild, uncomplicated biliary pain. Pregnant patients and patients on anticoagulants should not undergo lithotripsy. Because only cholesterol stones are reliably cleared by the addition of oral dissolution therapy, stones should have radiographic features, such as radiolucency, suggestive of cholesterol stones.

Side effects of lithotripsy include petechiae of the skin at the site of shock-wave delivery (8%), hematuria (4%), and liver hematomas (<1%). No long-term liver biochemical abnormalities have been noted. Biliary pain develops in approximately one third of patients; cystic duct obstruction develops in 5%; and complications of stone passage, such as biliary pancreatitis, develop in less than 2%.

Lithotripsy is more cost-effective in the elderly than in the young and less cost- effective in patients with multiple stones than in those with a single stone.

OPERATIVE MANAGEMENT

Cholecystectomy is one of the most common major abdominal operations. Cholecystectomy can be performed by open and laparoscopic methods.

The indications for cholecystectomy are the same for both techniques.[31] These include:

1. Symptomatic gallstones causing
   i. Repeated episodes of biliarypain
   ii. Mucocele of thegallbladder
   iii. Choledocholithiasis with extra-hepaticcholestasis
   iv. Biliarypancreatitis
   v. Gallstoneileus
2. Cholecystitis and its complications - acute calculous / acalculous cholecystitis, chronic cholecystitis, empyema gallbladder, gangrenous cholecystitis, gallbladder perforation.
3. Asymptomatic cholelithiasis: Laparoscopic cholecystectomy is indicated in asymptomatic cholelithiasis in certain selectiveindications:
   i. Patients undergoing bariatricsurgery.
   ii. Diabetics.
   iii. Renaltransplantation.
   iv. Children.
   v. Those with hemolytic diseases with multiple pigmentstones.

4. ‘Gallstone dyspepsia’: Patients with ‘classic’ biliary pain without evidence of gallstone may benefit from cholecystectomy. Biliary dyskinesia can be detected by objective measurements of changes in gallbladder volumes(ejection fraction <35%) or reproduction of the pain on consumption of fatty meal or cholecystokinin infusion. These patients may benefit from surgery. However, one should warn the patient that 20-30% of patients operated for dyspepsia have a persistence of symptoms.

5. Gallbladderpolyps.

Traditionally, open cholecystectomy has been the gold standard for all patients with symptomatic gallstonedisease.[32]

LAPAROSCOPIC CHOLECYCTECTOMY [39,40]

Indications:

The indications for laparoscopic cholecystectomy remain the same as for open cholecystectomy.

Contra-indications:

1. Patients unfit for general anaesthesia.
2. Significant portal hypertension.
3. Uncorrectable coagulopathy.
4. Patients with proven or suspected gallbladder cancer.
5. Surgeon inexperienced in laparoscopic surgery.

Pre-operative Work-up:

1. Routine blood tests, including liver function tests.
2. Ultrasonography.
3. Upper GI endoscopy - to identify patients with acid peptic disorders or hiatus hernia
4. DVT prophylaxis in high risk patients.

Drawbacks of laparoscopic cholecystectomy:

1. The incidence of bile duct injuries is more as compared to open cholecystectomy.
2. The operating time required for laparoscopy cholecystectomy is more as compared to open method.

Advantages:

1. Laparoscopic cholecystectomy is associated with a lower risk of surgical site infection than open method, even after adjustment for other risk factors.
2. Post operative pulmonary function was impaired less after laparoscopic than after open cholecystectomies.
3. Postoperative pain is less.

LAPARASCOPY CHOLECYSTECTOMY

Anaesthesia:

General anaesthesia is the preferred anaesthetic method for patients undergoing most therapeutic laparoscopic surgical procedures. Two advantages of general anaesthesia as compared to other types of anaesthesia are two folds:

1. It allows for complete control of the patient's ventilation, which might otherwise be compromised by systemic absorption of CO_2 and increased diaphragmatic pressure from the pneumoperitoneum.
2. It enables complete relaxation of the abdominal wall muscles necessary for adequately maintaining pneumoperitoneum.

Patient Position and Room Set-up:

North American Approach: The patient is kept supine in anti-Trendelenburg position (15^0 head up tilt) with left lateral tilt ($15\text{-}20^0$). This ensures that the bowel and omentum falls down and medially, away from the operative site. The operating surgeon and camera surgeon stand on the left of the patient while the assistant surgeon stands on the right of the patient. The monitor is kept beyond the right shoulder of the patient facing the operating surgeon. An additional monitor may be kept beyond the left shoulder of the patient for the assistant surgeon.

The camera port (10 mm) is placed in the midline, usually through the umbilicus. The remaining trocars are: 10 mm in the epigastric region, 5 mm in the mid-clavicular line sub-costally and 5 mm in the anterior axillary line

subcostally.

French/European Approach: The patient is in semi-lithotomy anti-Trendelenburg position with the legs in Allen stirrups such that the thighs are almost parallel to the ground to avoid interference with the manipulations of the operating instruments. The operating surgeon stands between the legs of the patient with the camera surgeon on the right of the patient and the assistant on the left of the patient.

The camera port placement remains the same as in the North American approach. Epigastric port (5 mm) is placed to allow retraction by the assistant. The right hand working port (10 mm) is placed in the left hypochondrium or in the midline between the camera port and the epigastric port. The left hand working port (5 mm) is placed in the right hypochondrium.

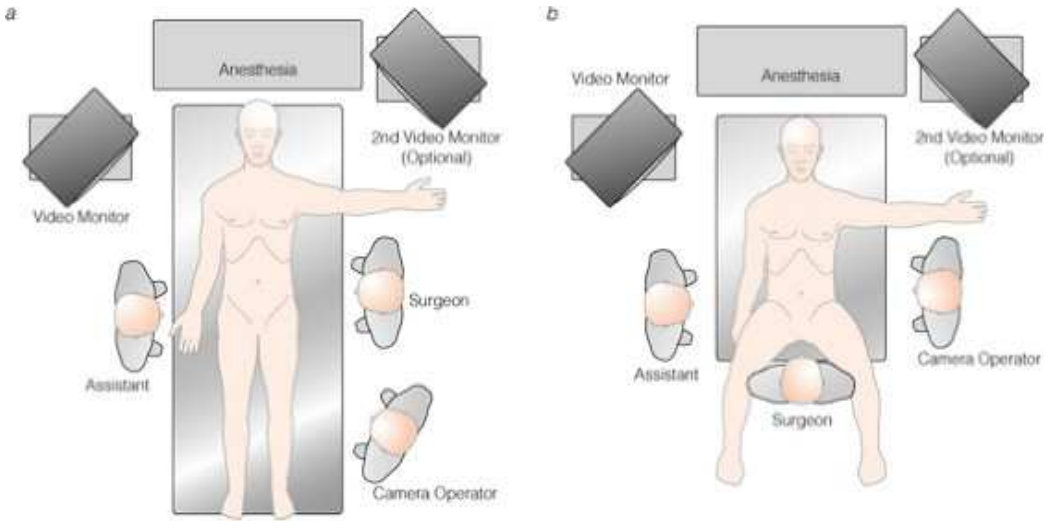


Figure 42: Shown are the positions of the surgeon, the camera operator, and the assistant in the OR according to (a) North American positioning and (b) European positioning

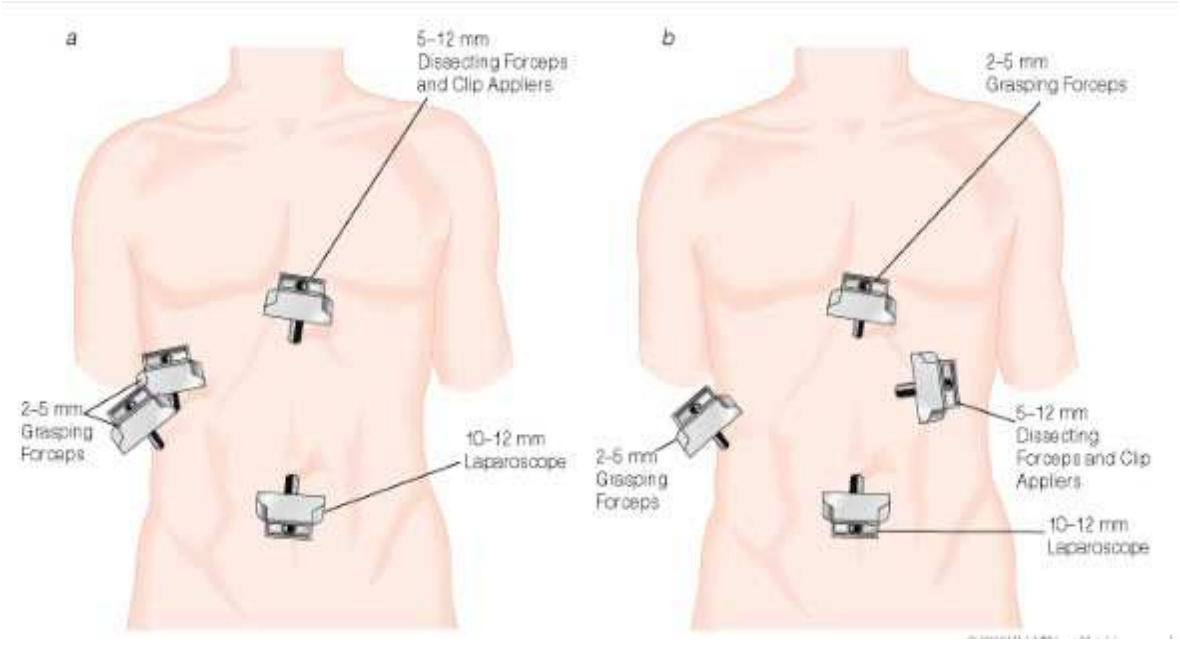


Figure 43: Differences between typical North American practice (a) and typical European practice (b) with respect to the placement of the trocars and the instruments inserted through each port.

Technique:

1. Pneumoperitoneum and portplacement:

Patient is positioned in supine with 10 to 20 degree head down to displace the intestines cranially. In the absence of operative scar, periumbilical site (thinnest site) is the most preferred site for Veress needle insertion. Depending on the shape of umbilicus, either a transverse or vertical stab is made with a number 15 or 11 knife. The shaft of the Veress needle should be held by the right hand, keeping the distal length of the needle tip just adequate to traverse the entire thickness of the abdomen wall. While inserting the needle, the little

finger and ulnar border of the right palm is propped against the abdomen.

The abdominal wall is lifted midway between the pubic symphysis and umbilicus by the left hand .The Veress needle is inserted either at a 45 degree caudal angle to the abdominal wall (in the asthenic or minimally obese patient) or perpendicular (in the markedly obese patients).

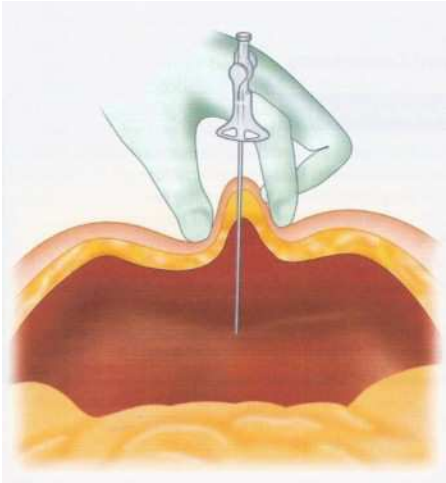


Figure 44: Veress needle insertion

Several maneuvers should be carried out to confirm the free intraperitoneal position of the needle. First, the needle is aspirated and irrigated to demonstrate the absence of return of blood or bowel contents and a free flow of fluid. Second, a saline drop test is performed in which the needle is filled with saline and fluid is demonstrated to flow freely by gravity into the peritoneal cavity as negative pressure is generated by lifting the abdominal wall. Finally, the needle is moved back and forth, which indicates that the tip is free within the peritoneal cavity.

The needle is connected to the insufflator and CO_2 is instilled at a rate of 1 L/min. The opening pressure recorded on the insufflator should be < 10 mmHg. Initial pressures of 10 mmHg or higher may indicate the placement of the needle in the pre- peritoneal or other closed space. Upon insufflating approximately 1L of CO_2, increased tympany in all four quadrants of the abdomen is confirmed, and the flow rate may be increased. Although high flow insufflators are designed to deliver flow rates of up to 8 to 10 L/min, the maximum flow rate through the small caliber Veress needle is approximately 2.5 L/min. Once the intra-abdominal pressure has reached 15 mmHg, generally requiring 3 to 6 L of CO_2, the Veress needle is removed, and the trocar is inserted through the same site.

The trocar is grasped firmly in the palm of one hand and inserted using gently firm pressure while elevating the abdominal wall with the other hand or with towel clips. Once the port is in, the inner trocar is removed, leaving the outer cannula and sheath in place. Return of CO_2 gas is confirmed by opening either the stopcock or flapper valve on the port and then connecting the insufflation line to the sheath. The video telescope is inserted and a general inspection of the peritoneal cavity, including underlying viscera and retroperitoneum, is carried out to assess for visceral injury.

The patient is placed in the anti-Trendelenburg position so that the intestines and viscera will fall downwards and to the left. The gallbladder is inspected. The remaining three trocars are inserted under vision.

The epigastric port (10 mm) is inserted in the midline just below the liver edge or the costal margin, whichever is lower. The trocar is thrust in a rotatory movement so that it pierces the fascia and reaches the pre-peritoneal space. Then, it is turned right so that it enters the peritoneum at the base of the falciform ligament. This maneuver serves two purposes: (a) The trocar avoids injuring a vessel which sometimes runs in the free edge of the falciform ligament. (b) The instruments through this port do not suffer interference from a falciform ligament hanging in front ofthem.

The mid-clavicular port (5 mm) is introduced at the same level, i.e., just below the liver edge or the costal margin, whichever is lower, right over the fundus of the gallbladder.

The lateral most port (5 mm) is introduced at the same level and just anterior to the lateral peritoneal attachment of the ascending colon.

Additional ports are sometimes required and may be placed as follows:

A. Left lumbar 5 or 10 mm for three prong or flat blade retractor for downward traction of the colon, omentum and duodenum. This maneuver gives wide exposure of thehilum.

B. 5 mm port midway between epigastric and right mid-clavicular ports for lifting the quadrate lobe using blunt tipped retractor, e.g. cirrhosis of the liver, left lobe gallbladder.

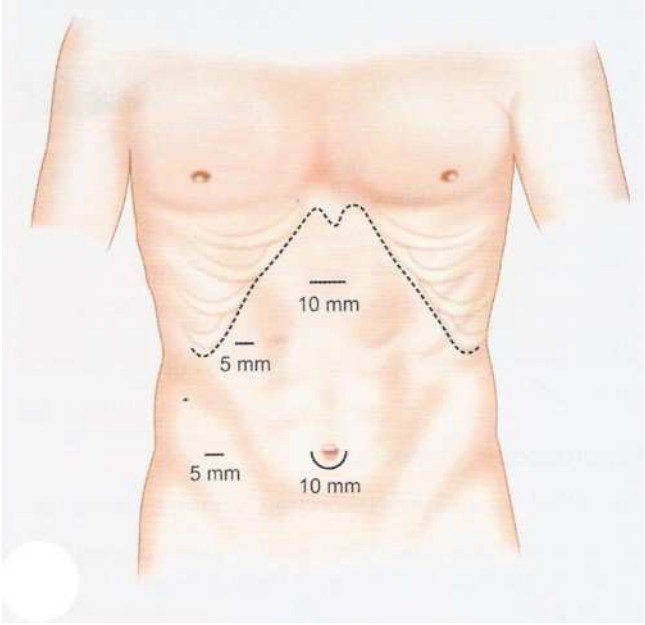


Figure 45: Port position for laparoscopic cholecystectomy

2. Initialdissection:

The fundus of the gallbladder is held with a ratcheted grasper and retracted by the assistant in a cranial direction, which lifts the right lobe of the liver and exposes the Calot's triangle and hilum of the liver.

Adhesions to the underside of the liver and gallbladder are carefully taken down beginning near the hilus and proceeding down towards the neck. The adhesions should be retracted downwards with the left hand grasper, to expose the plane of division. Adhesions may contain omentum, colon, stomach, and duodenum and hence must be dissected withcare.

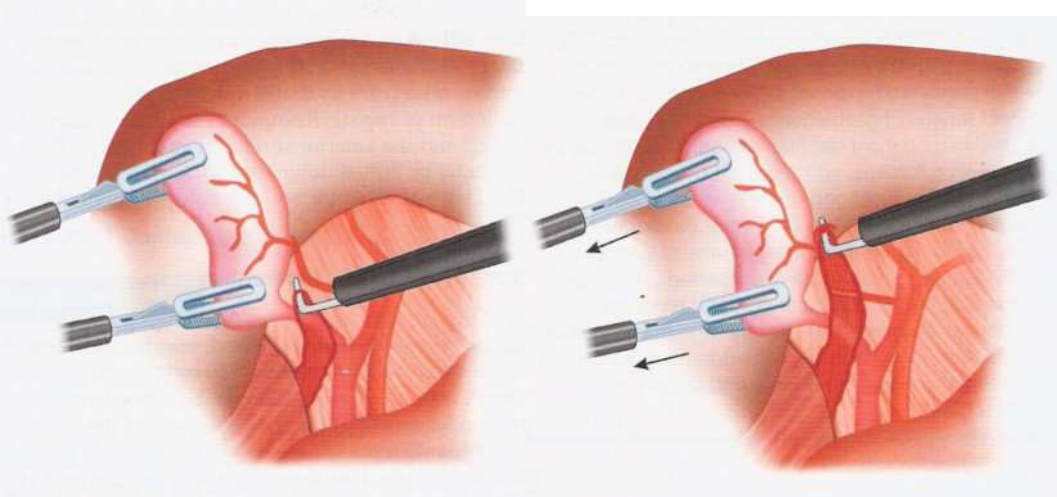


Fig 46: Dissection of cystic duct Figure 47: Dissection of cystic artery

3. Dissection of cholecysto-hepatic triangle:

An atraumatic (dolphin-nosed) non-locking grasper is introduced through the left hand working port to hold the infundibulum and retract it downwards and to the right. Thus, the hepatocystic triangle is widened and opened up and the structures are placed under tension. By retracting the infundibular grasper laterally, the anterior aspect of the Calot's triangle is exposed. By retracting the infundibular grasper antero-medially, the posterior aspect of the Calot's triangle is exposed.

The dissection is begun on the infundibulum of the gallbladder. Using a Maryland's forceps introduced through the epigastric port, the peritoneum of the infundibulum is held and breached by giving very small bursts of cautery current. By a combination of cautery and blunt dissection, the peritoneum on the anterior and posterior surface is stripped down patiently always being

careful to remain on the gallbladder side. The infundibular grasper is moved inferolaterally and superomedially (flagtechnique) to aid this dissection on the anterior and posterior surface of cholecysto-hepatic triangle respectively. The cholecysto-hepatic triangle is thus exposed.

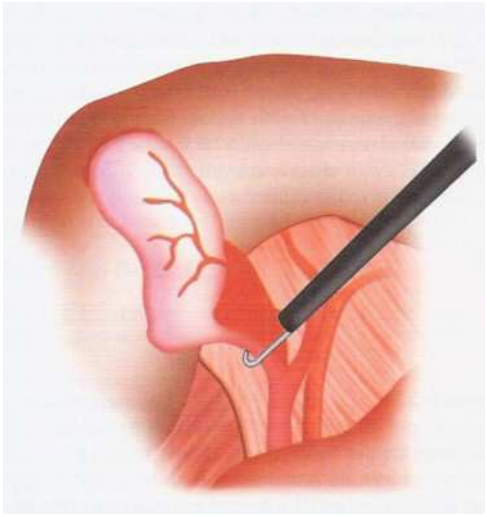


Fig 48: Dissection of cystic pedicle

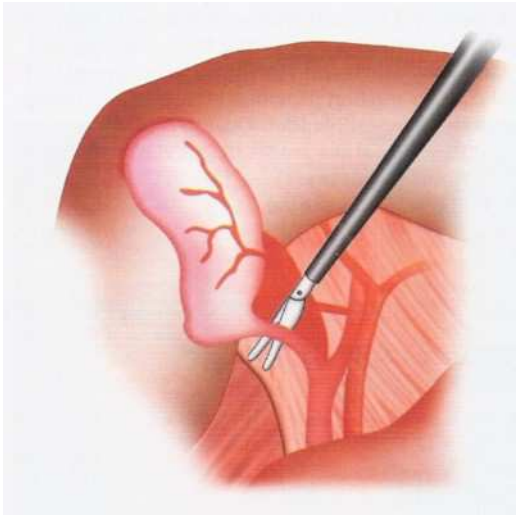


Fig 49: Dissection of cystic duct by blunt dissection

4. Identification of the cystic duct and artery:

Now comes the most critical step of the operation - the identification of the cystic duct and artery. There are two well-described methods for ductal identification in laparoscopic cholecystectomy.

The first method has been referred to as the “infundibular” or “infundibular- cystic” technique. In this method the cystic duct is isolated by dissection on the front and the back of the triangle of Calot and once isolated it is traced on to the gallbladder. Conclusive identification, i.e., the anatomic rationale for identification, occurs as a result of seeing the characteristic flare,

as the cystic duct widens to become the gallbladder infundibulum. Often this is referred to as seeing a funnel shape i.e. the gallbladder should be seen to funnel down to terminate in the cystic duct. The infundibular method is the one usually found in texts describing the technique of laparoscopic cholecystectomy.

The second method is the “critical view of safety” technique, which was described in 1995.[42] This method requires complete dissection of the cholecystohepatic triangle and separation of the base of the gallbladder infundibulum from the liver bed. The anatomic rationale for identification of the cystic structures results from the fact that there are two, and only two, structures entering the gallbladder, which is otherwise still attached only by the upper part of the liver bed. The triangle of Calot is dissected free of all tissue except for cystic duct and artery, and the base of the liver bed is exposed. When this view is achieved, the two structures entering the gallbladder can only be the cystic duct and artery. It is not necessary to see the common bileduct.[43]

The cystic duct is identified at the junction with the gallbladder (safety zone) and followed down for an adequate length for cholangiography if desired. It is not always necessary to identify and dissect out the cystic-common duct junction (danger zone).

Cystic artery is identified along with its anterior and posterior branches by blunt dissection using curved dissector within the cystic triangle avoiding any

potential avulsion of the cystic artery off the right hepatic artery. The cystic node of Lund sometimes overlies the cystic artery. Attention is given to identify any unusual vascular or biliary tree anomalies. The main trunk of the cystic artery should be ligated and divided. Widely placed anterior and posterior branches areclipped individually and divided. Blind application of clips within the Calot's triangle should be avoided.

Both the cystic duct and the cystic artery are clipped, two clips on the cystic duct side and one clip on the gallbladder side. Though it is desirable to divide the artery before the duct, in selected situations, duct needs to be divided to expose cystic artery, hepatic artery, etc, and care is taken not to give excessive traction till the cystic artery is clipped and divided.

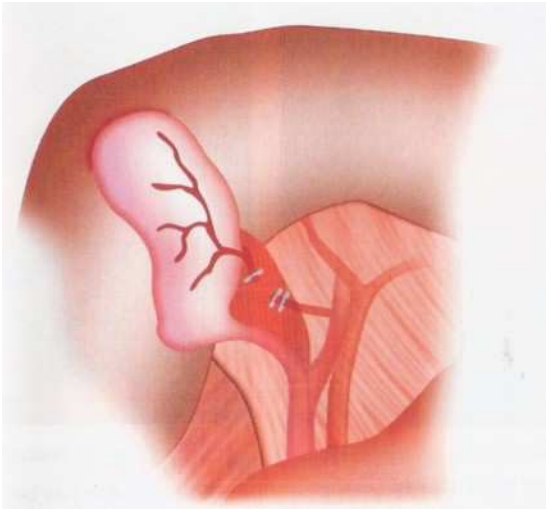


Fig 50: Clipping of cystic artery

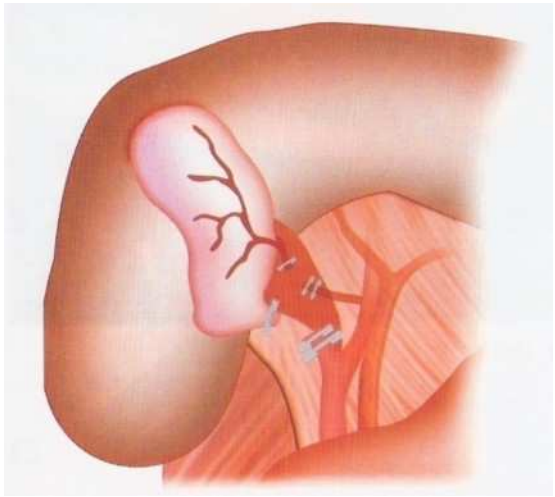


Fig 51: Clipping of cystic duct

5. Detachment of the gallbladder from the liver:

The gallbladder can be detached from the liver bed using a variety of instruments - spatula with monopolar cautery, hook with monopolar cautery, scissors with monopolar cautery or Harmonic Scalpel. Surgeon’s experience and familiarity with a particular device is the most important aspect of choosing the best instrument for this purpose.

Care should be taken to stay away from the porta hepatis and the liver bed and to avoid perforating the gallbladder. The infundibular grasper is used to elevate the gallbladder and alternately twist it to the left (medial rotation) and to the right (lateral rotation). A hook cautery is very useful for this phase of the operation.

Prior to complete detachment of the gallbladder, the liver bed is inspected for adequate hemostasis or bile leak. The cystic duct remnant and cystic artery stumps are examined once again to ensure that the previously placed clips or sutures remain secure. Any minor oozing from the liver bed is controlled by application of cautery. After achieving hemostasis, the remaining separation is carried out and gallbladder is extracted.

Figure 52: Dissection of gallbladder from its bed

6. Extraction of thegallbladder:

The extraction of the gallbladder can be carried out through the umbilicus or the epigastric port. A claw-shaped gallbladder extraction forceps is introduced and used to grasp the neck of the gallbladder. The forceps, cannula and the neck of the gallbladder are pulled out of the skin opening.If the gallbladder is too distended, the neck is opened and suction cannula is inserted to suck out the bile and if necessary, the stones are debulked through fragmentation by using a sponge holder. If the gallbladder is thick, preventing its extraction fascial incision is extended to facilitate its removal.

7. Final inspection andirrigation:

After gallbladder extraction, the epigastric port is replaced and the surgical site is inspected for bleeding. A thorough wash is given to the gallbladder bed, Morrison's pouch, paracolic gutter and perihepatic areas with saline which is meticulously suctioned out.

8. Drainage andClosure:

If a drain is needed, it can be placed through the lateral-most port. A size 14F Romovac tube which goes through a 5 mm trocar is usually sufficient. If larger drainage tube is needed, it should be placed inside the peritoneal cavity through the epigastric port and brought out by a grasper through the lateral-most port in a reverse fashion.

The trocars are removed under direct vision to check that there is no bleeding from the trocar sites. Pneumoperitoneum is evacuated. The fascia of the 10 mm ports is closed with vicryl suture using port closure needle. Fascial closure is not required for the 5 mm ports. Skin closure is done using 3-0 vicryl subcuticular stitch/skinclip.

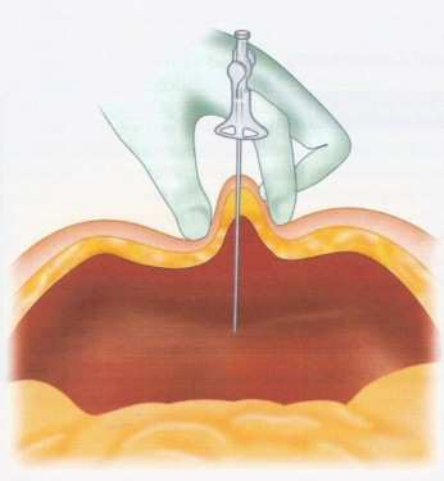


Figure 44: Veress needle insertion

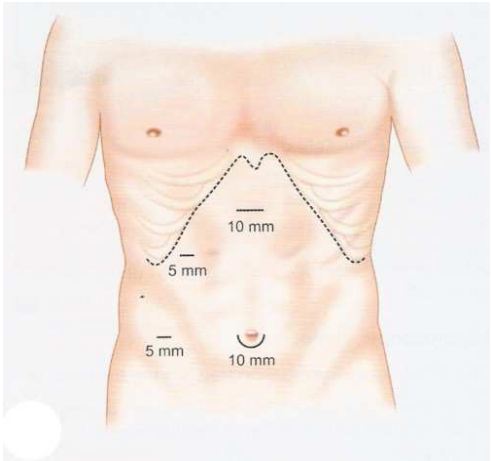


Figure 45: Port position for laparoscopic cholecystectomy

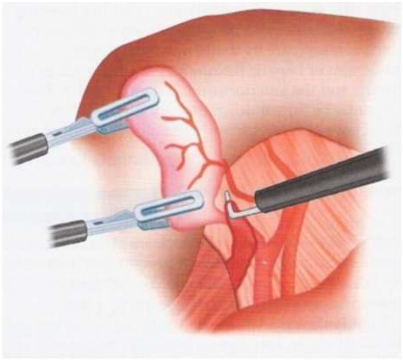


Fig 46: Dissection of cystic duct

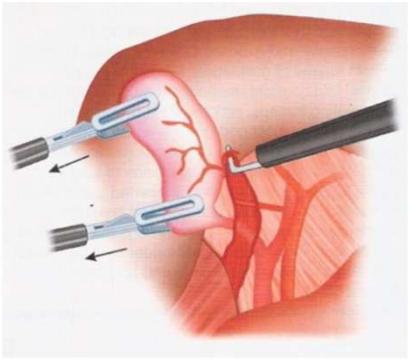


Figure 47: Dissection of cystic artery

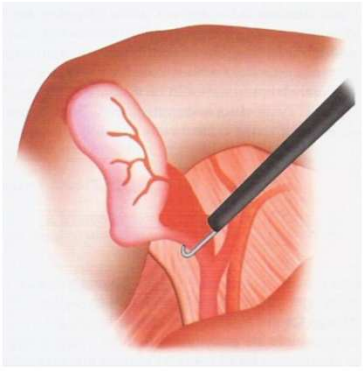


Fig 48: Dissection of cystic pedicle

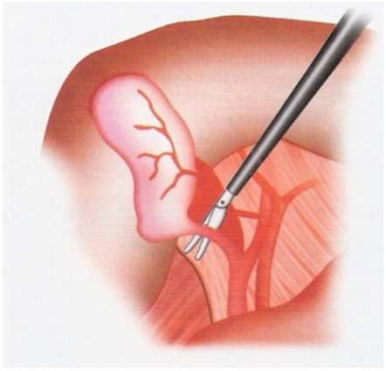


Fig 49: Dissection of cystic duct by blunt dissection

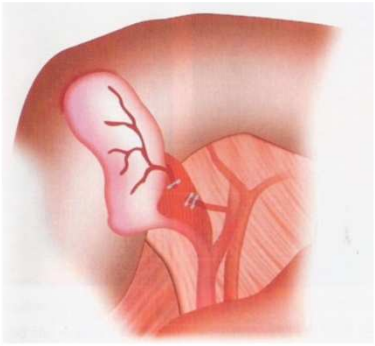


Fig 50: Clipping of cystic artery

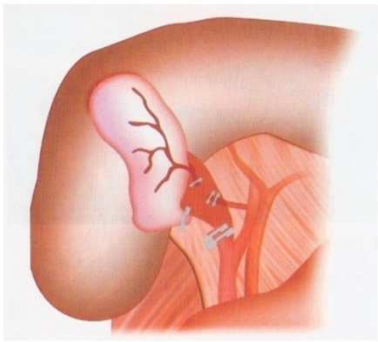
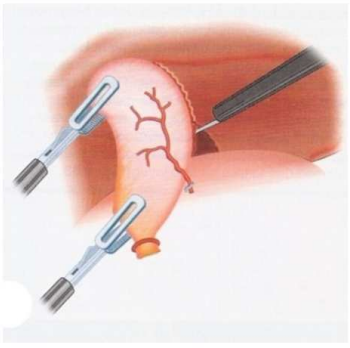


Fig 51: Clipping of cystic duct



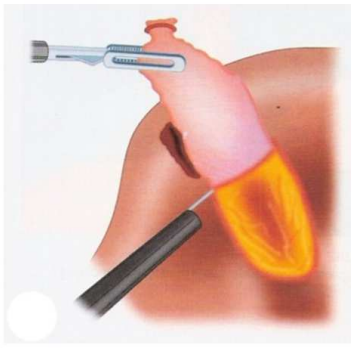


Figure 52: Dissection of gallbladder from its bed

COMPLICATIONS:

1) Trocar injuries:

2) Bleeding:

3) Injury to bileducts:

4) Stone and Bile spillage

METHODOLOGY

METHODOLOGY

The present study is a comparative study of 394 cases of cholelithiasis who undergone laparoscopic cholecystectomy in the institute of general surgery, MMC & RGGGH, Chennai, during study period of may 2017 to October 2018. These cases were selected based on inclusion criteria and were randomized using software after taking valid informed consent (Annexure)

INCLUSION CRITERIA

Adults > 18 years of age undergoing elective laparoscopic cholecystectomy for cholelithiasis

EXCLUSION CRITERIA

1. Cholangitis

2. Acute cholecystitis

3. Lap converted open cholecystectomy

4 Recent onset acute cholecystitis

The general bio-data of patient regarding his name, age, sex, occupation, socio-economic status and address were collected. A detailed history was taken with special reference to duration of abdominal pain(RUQ pain or epigastric pain),dyspepsia, indigestion, its periodicity, its aggravation by fatty meals and relief by oral or parenteral analgesics. Any significant past history was also enquired. A relevant general physical examination, abdominal and systemic

examination was done.

Pre-operative work up included a complete blood count, blood sugar, blood urea, serum creatinine, liver function tests, hepatitis profile, X-ray chest and ultrasound of abdomen. Ultrasonogram was routinely performed on all patients to confirm the clinical diagnosis of cholelithiasis with number of calculus and size of calculus, gall- bladder wall thickness (>4mm was considered abnormal), pericholecystic collection.

A routine pre-anaesthetic checkup was done. A fully explained well informed consent was taken. A nasogastric tube was placed in all cases for gastric decompression to prevent trocar injury. All patients received prophylactic pre-op antibiotics (Inj. Cefotaxim 1gm IV).

The patients were operated by different senior surgeons. The operation was performed with standard four port technique, using carbon dioxide for peritoneal cavity insufflation. The Veress technique was used to obtain pneumoperitoneum. Cystic artery and cystic duct were skeletinized and clamped with metallic clips separately. Following gall bladder removal, No.16 romovac suction drain was placed in all cases. All patients had oral liquids followed by food from 3rd day after surgery, provided there was no nausea and vomiting.

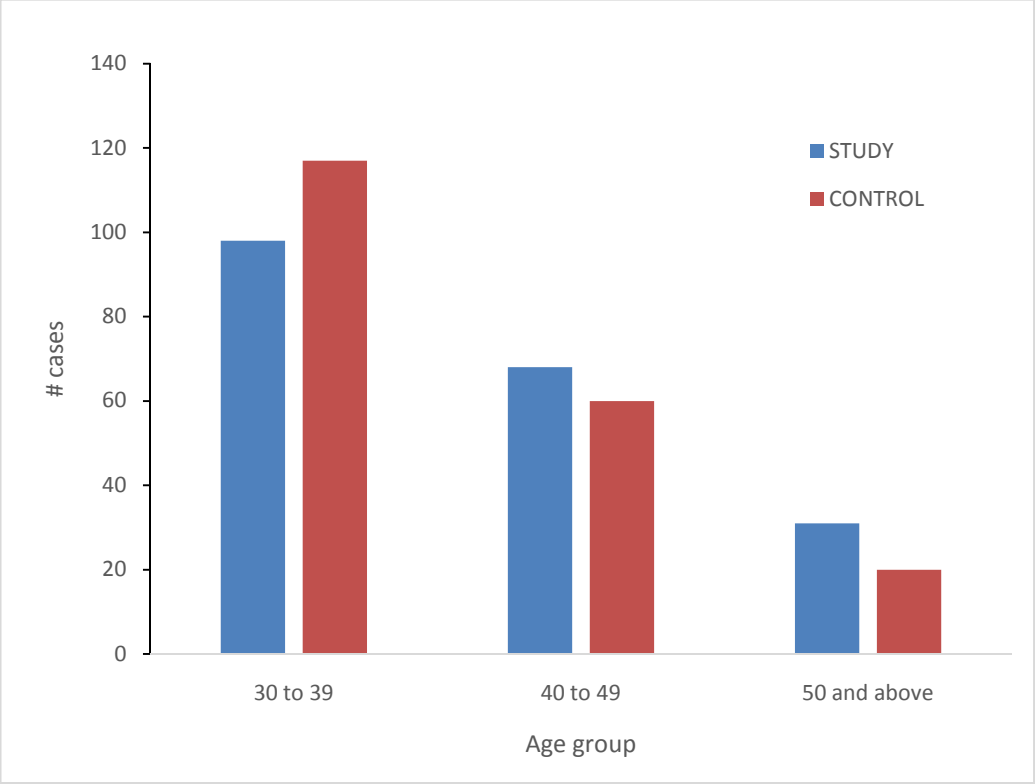
RESULTS

RESULTS

A total of 394 patients eligible for the study were selected. All the patients who undergone elective laparoscopic cholecystectomy categorised into study group and control group. Study group receiving prophylactic intravenous antibiotic (1gm cefotaxim) at the time of induction of anaesthesia alone. Control group receiving prophylactic intravenous antibiotic at the time of induction of anaesthesia which will be continued in the post operative period till discharge. Patients were followed in the post operative period with regard to surgical site infections.

AGE INCIDENCE

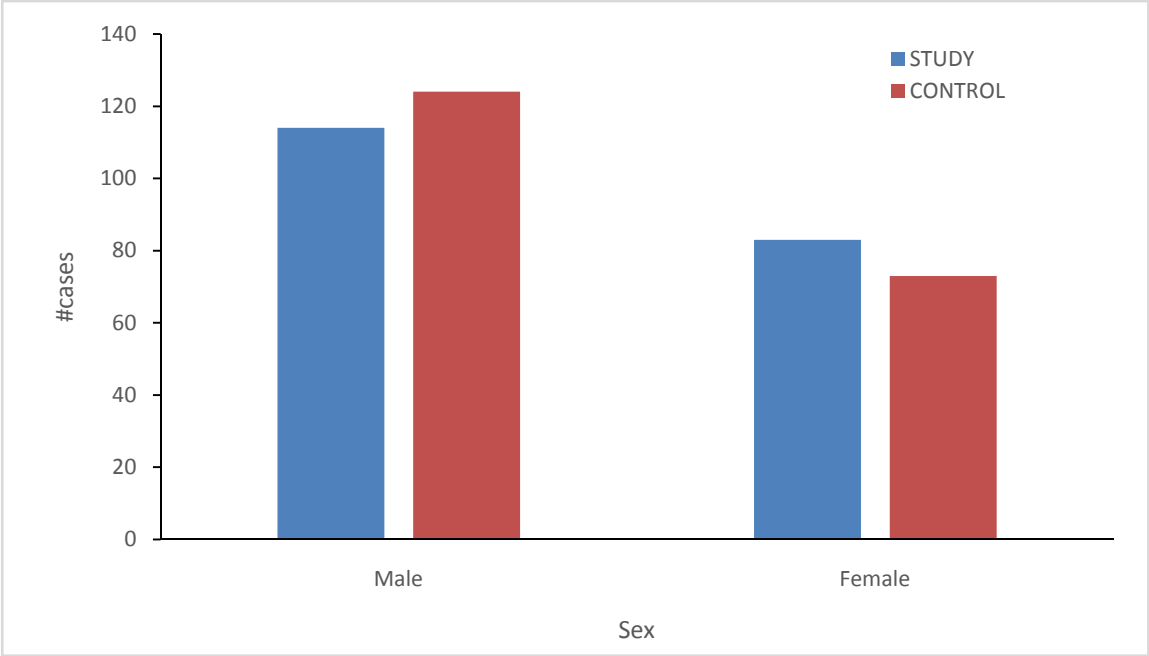
		Study group (N=197)		Control group (N=197)		
Characteristics		n	%	N	%	p value
AGE (in years)	30 to 39	98	49.7	117	59.4	p<0.05
	40 to 49	68	34.5	60	30.5	
	50 and above	31	15.7	20	10.2	



Mean age in the study group is 41 years, in the control group is 38 years, the age group of patients ranges from 30 to 58 years. In study group 49.7% of patients between 30 to 39 years of age. In control group 59.4% of patients from 30 to 39 years of age. patients are allocated in the study and control without statistically significant.

SEX INCIDENCE:

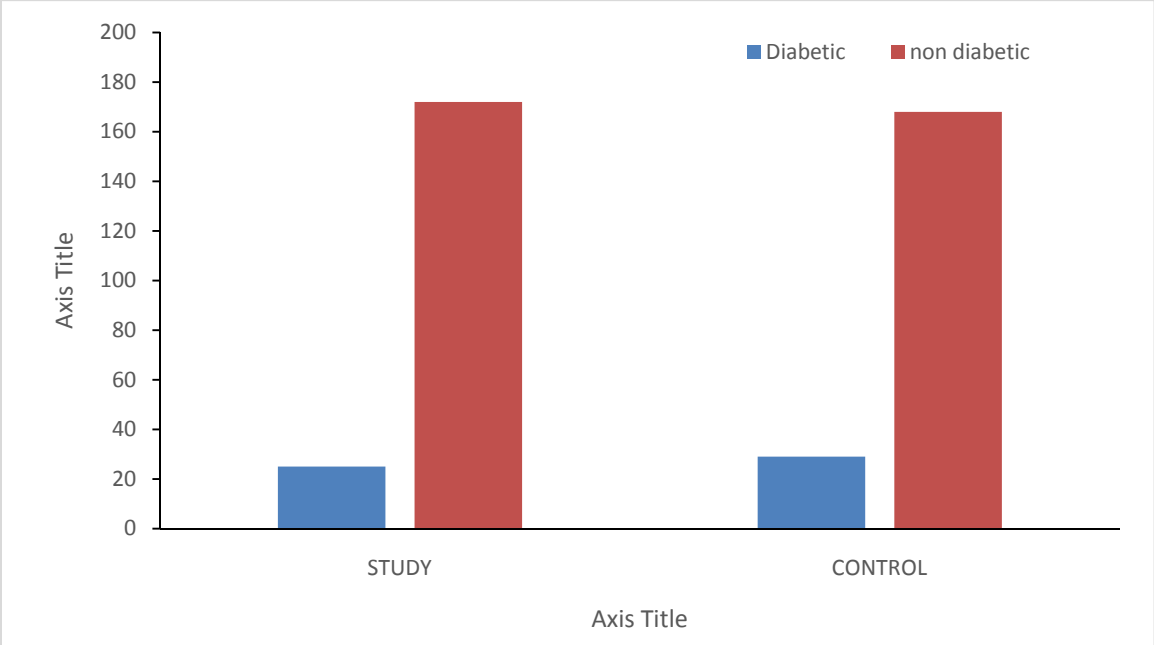
Characteristics		STUDY (N=197)		CONTROL(N=197)		
		n	%	n	%	p value
SEX	Male	114	57.9	124	62.9	p>0.05
	Female	83	42.1	73	37.1	



In the study group 114 cases(57.9%) are male and 83 cases (42.1%) are female . In the control group 124 cases (62.9%) are male and 73 cases (37.1%) are female.

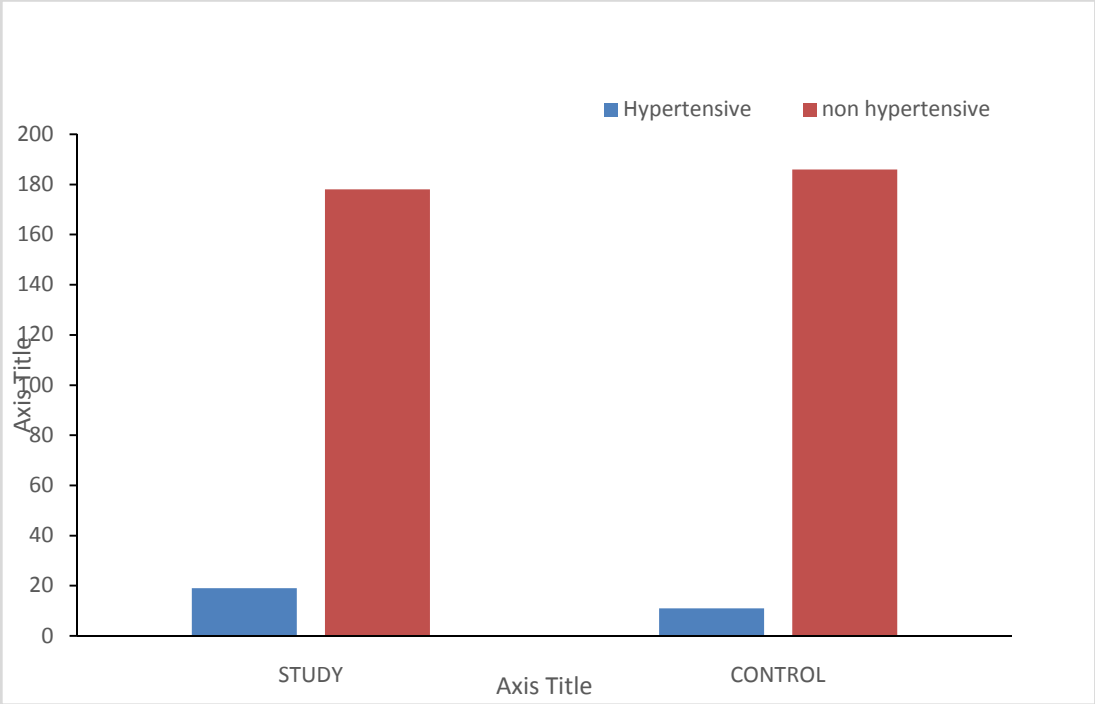
COMORBIDITIES INCIDENCE:

		STUDY (N=197)		CONTROL(N=197)		
Characteristics		n	%	n	%	p value
DIABETES MELLITUS	Diabetic	25	12.7	29	14.7	p<0.05
	non diabetic	172	87.3	168	85.3	



In the study group 25 patients are diabetic in the control group 29 patients are diabetic. When analysed statistically no significant association between the presence of diabetes and wound infection could be obtained.

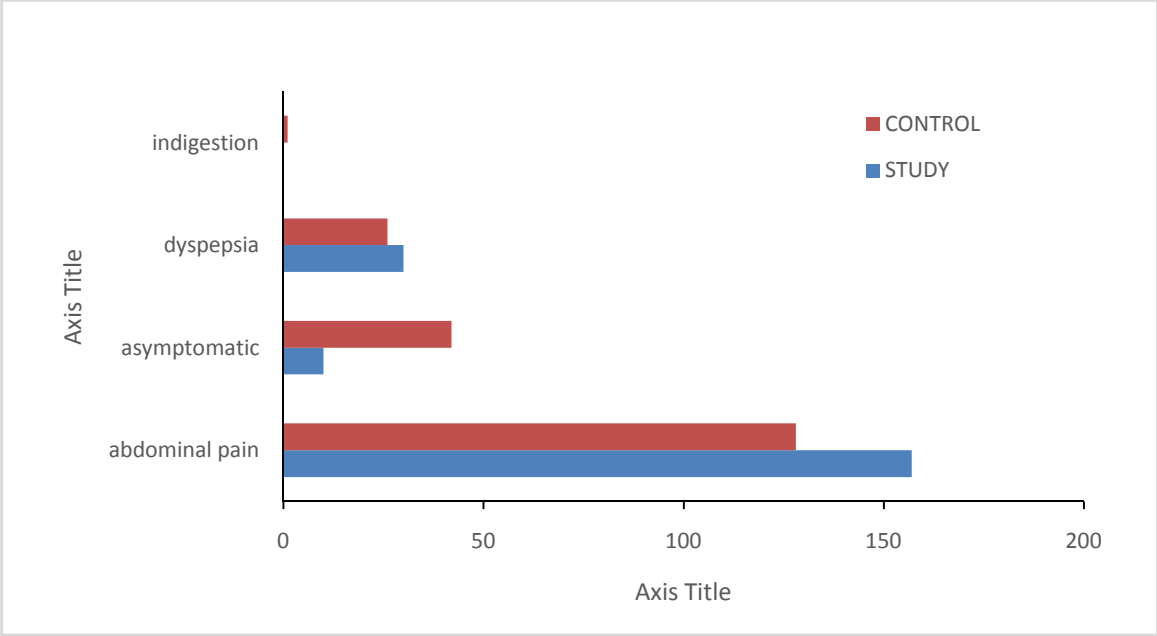
		Single dose (N=197)		Multi dose (N=197)		
Characteristics		N	%	n	%	p value
Hypertension	Hypertensive	19	9.6	11	5.6	p>0.05
	non hypertensive	178	90.4	186	94.4	



In the study group 19 patients are hypertensive which is 9.6%. in the control group 11 patients are hypertensive which is 5.6%. when analysed statistically no significant association between the presence of hypertension and wound infection could be obtained

PRESENTING COMPLAINTS INCIDENCE:

		STUDY (N=197)		CONTROL (N=197)		
Characteristics		N	%	N	%	p value
presenting complaint	abdominal pain	157	79.7	128	65.0	p>0.05
	Asymptomatic	10	5.1	42	21.3	
	Dyspepsia	30	15.2	26	13.2	
	Indigestion	0	0.0	1	0.5	

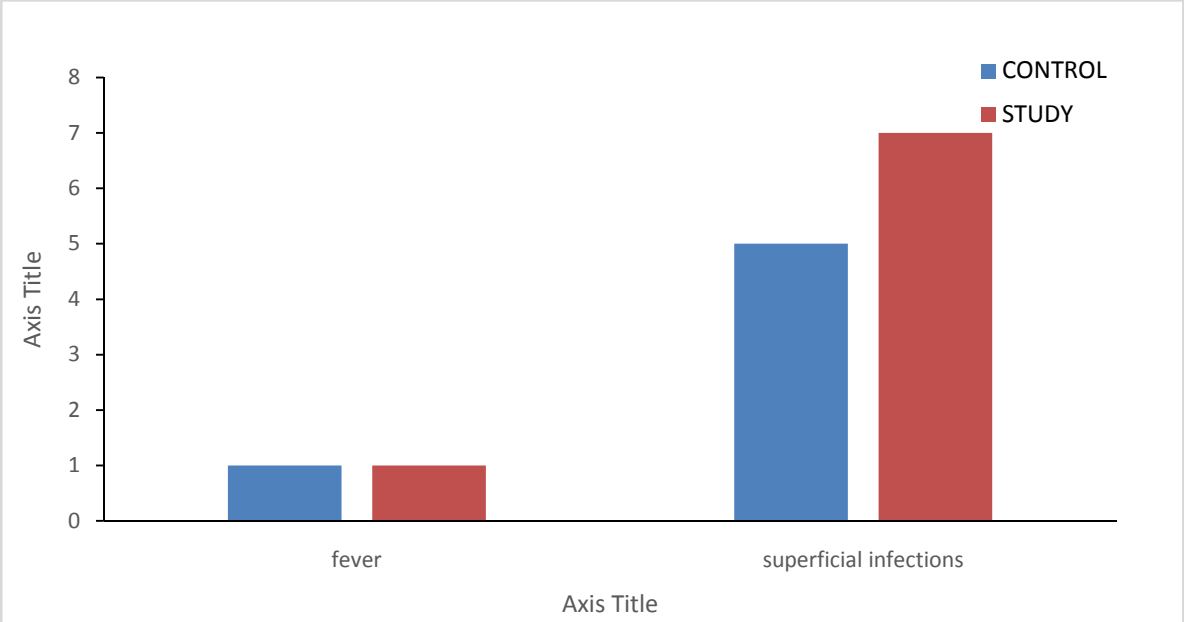


Most of the patients are presented with abdominal pain as a main complaint in both study and control group. 79.7% of patients in the study group 65% of patients in the control presented with abdominal pain.5.1% of patients in the study group and 21.3% of patients in the control group are asymptomatic.15.2% of patients in the study group, 13.2% of patients in the control group are presented with dyspepsia.

POST OPERATIVE COMPLICATIONS

		STUDY (N=197)		CONTROL (N=197)		
		N	%	N	%	
Complications	Developed	8	4.2	6	3.0	P<0.05
	not developed	190	95.8	191	97.0	

	STUDY(N=197)		CONTROL(N=197)	
complication	n	%	N	%
Fever	1	1.5	1	0.5
Superficial infections (pus discharge from port site)	7	3.6	5	2.5
deep infection	0	0	0	0
Seroma formation	0	0	0	0
Others	0	0	0	0



Post operative complications are monitored. In study group 1 patient was developed fever, in the control group 1 patient developed fever.in this study surgical site infections were taken into account. In the study group 7 patients (3.6%) developed pus discharge from port site which is considered as superficial infections ,in the control group 5 patients (2.5%) developed pus discharge. In all cases deep infections are ruled out by doing ultrasonography. There is no seroma formation in both study and control group. I concluded that surgical site infection in the single IV antiobiotic group is 3.6% where as in the control group, in which IV antibiotics were continued in the post operative period till discharge is 2.5%.

DISCUSSION

DISCUSSION

It is well documented that prophylactic antibiotic coverage of most 'clean contaminated' surgical procedures can significantly prevent infectious complications, including wound infections, thereby affecting the overall mortality and morbidity. However the benefit of antibiotic prophylaxis in other 'clean surgical procedures, such as laparoscopic cholecystectomy, has been questionable. The low rate of wound infections and the straight forward treatment, if they occur at all, are the main arguments against routine antibiotic coverage during laparoscopic cholecystectomy. Laparoscopic cholecystectomy is an elective clean operations, and the post operative wound infections would be very low. Prophylaxis in clean operations has been shown to be of value in other areas of surgery such as trauma and vascular surgery but in laparoscopic cholecystectomy, its benefits remains uncertain. Due to the unknown impact on bacterial resistance, waldvogel and associates suggested that the routine use of antibiotic prophylaxis should be discouraged.

The aim of the study was to assess the antibiotic therapy in preventing post -operative complications in laparoscopic cholecystectomy. The mean age of the study is 41 years in study group and 38 years in control group. The percentage of the females in the study group is 42.1% and in the control group is 37.1%. the percentage of males in the study group is 57.9% and in the control group is 62.9%. symptomatic cholelithiasis is most commontly present in the 5^{th} decade with significant female prepondrence. Pain abdomen is was the commonest presenting symptom which occure 79.7% in the study group

and 65% in the control group. In my study 12.7% of patients in study group and 14.7% of patients in the control group were diabetic and 9.6% of patients in the study group and 5.6% of patients in the control group were hypertensive. There are several risk factors that are significantly associated with an increased incidence of infective complications in patients who undergo elective laparoscopic cholecystectomy, one of them is the presence of diabetic mellitus. Out of 197 patients in the study group 7 of them developed pus discharge from port site with incidence of about 3.6% and in the control group 5 patients out of 197 patients are developed pus discharge from port site with incidence of about 2.5%. all others had completely healed wound. These differences yielded a P>0.05 which is statistically insignificant, thereby illustrating that the rates of wound infection in patients given only a single shot of iv antiobiotic, and in patients given continuous post operative iv antibiotics is statistically insignificant.

In a randomized controlled trial on 417 patients undergoing laparoscopic cholecysectomy, conducted by Gaur and Pujahari11, they reported an overall infection rate of 2.2 %, which is consistent with the results obtained in our study. All the infections healed before the availability of culture and sensitivity report without any specific therapy.

Our findings are also similar to the findings obtained by Pokharel and associates12, who stated that the use of prophylactic antibiotics is a factor for lower incidence of post-operative infection following laparoscopic cholecystectomy. Good surgical techniques and the judicious use of

prophylactic antibiotics are two major factors for decreasing the incidence of septic complications after biliary tract surgery.

In another study conducted by Mahmoud and associates to assess the role of antibiotic prophylaxis in elective laparoscopic cholecystectomy, they stated that antibiotic prophylaxis does not prevent wound infection in elective laparoscopic cholecystectomy. This is probably due to the fact that Mahmoud and associates excluded all patients with associated co-morbidities, like diabetes mellitus, hypertension etc. from their study.

They also concluded that the use of antibiotic prophylaxis is preferred to be restricted to high-risk patients such as patients with associated co-morbidities like diabetes mellitus. The rate of post-operative wound infection in our study was low (0.41%) and there was no significant difference between wound infection in patients receiving prophylactic antibiotics and post-operative antibiotics. This can be attributed to the following reasons.

- Good surgical technique
- Better handling of tissues
- Strict adherence to aseptic precautions
- Experienced laparoscopic surgeons

In a study conducted by Gaur and Pujahari11, they concluded that the umbilicus is the commonest site for sepsis following laparoscopic cholecystectomy. This may be because the deep umbilical depression is

sometimes difficult to clean. Also, it may be due to the routine protocol of our unit to extract the gall bladder through the umbilical port. Colizza and associates14 also stated that the umbilicus is the commonest site for sepsis in elective laparoscopic choelcystectomy.

In a study conducted by Koc and associates10, it was stated that the presence of diabetes mellitus is a risk factor for the development of postoperative infective complications in patients undergoing elective laparoscopic cholecystectomy. The presence of diabetes mellitus is a known risk factor for biliary sepsis. The altered motility of the common bile duct muscles, which is secondary to autonomic neuropathy observed in diabetic patients, as well as increased lipid concentration in bile, are the elements that can cause an increased susceptibility to biliary sepsis in patients with diabetes.

CONCLUSION

CONCLUSION

Based on the findings of our study, it may be concluded that post operative antibiotics do not reduce post-operative infective complications after elective laparoscopic cholecystectomy for cholelithiasis. One single dose of prophylactic antibiotic, administered at induction of anaesthesia, is sufficient to prevent post operative infective complications in patient undergoing elective laparoscopic cholecystectomy.

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BIBLIOGRAPHY

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ANNEXURE

ANNEXURE

INFORMATION SHEET

TITLE :" **A COMPARATIVE STUDY ON ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY WITH AND WITHOUT PROPHYLACTIC ANTIMICROBIAL THERAPY"**

Name of Investigator : Dr.A.SURESHKUMAR

Name of Participant:

Purpose of Research: A comparative study on elective laparoscopic cholecystectomy with and without antimicrobial therapy

Study Design: Prospective study

Study Procedure: Patient will be subjected to clinical examination ,Routine investigations, USG abdomen, CECT abdomen, Endoscopy.

Prophylactic antibiotic IV dose

Elective laparoscopic cholecystectomy

Follow up

Possible Risks: No risks to the patient

Possible benefits

We can avoid unnecessary use of antibiotics and development of antibiotic resistance to the community.

Confidentiality of the information obtained from you: The privacy of the patients in the research will be maintained throughout the study. In the event of

any publication or presentation resulting from the research, no personally identifiable information will be shared

Can you decide to stop participating in the study: Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time

How will your decision to not participate in the study affect you: Your decision will not result in any loss of benefits to which you are otherwise entitled.

Signature of Investigator Signature of Participant

Date :

Place :

PATIENT CONSENT FORM

Study Detail	:	"A COMPARATIVE STUDY ON ELECTIVE LAPAROSCOPIC CHOLECYSTECTOMY WITH AND WITHOUT PROPHYLACTIC ANTIMICROBIAL THERAPY"
Study Centre	:	Rajiv Gandhi Government General Hospital, Chennai.
Patient's Name	:	
Patient's Age	:	

Patient may check (☑) these boxes

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction. ❑

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected. ❑

I understand that sponsor of the clinical study, others working on the sponsor's behalf, the Ethics committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published, ❑

unless as required under the law. I agree not to restrict the use of any data or results that arise from this study.

I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I suffer from any deterioration in my health or well being or any unexpected or unusual symptoms. ❑

I hereby consent to participate in this study ❑

I hereby give permission to undergo complete clinical examination and diagnostic tests including hematological, biochemical, radiological tests and to undergo treatment ❑

Signature/thumb impression	Signature of the Investigator
Patient's Name and Address:	Study Investigator's Name

QUESTIONAIRE

PATIENT DETAILS:

Name: Age: Sex:

IP No:

ON ADMISSION:

CHIEF COMPLAINTS:

DURATION:

ASSOCIATED COMPLAINTS:

CLINICAL EXAMINATION:

Pulse :	BP :
RR :	Temp :
Pallor :	Icterus :
CVS :	RS :
P/A :	CNS:

INVESTIGATIONS :

HB%				
PCV				
TC				
RBC				
PLATELETS				
RBS				
Urea				
Creatinine				
Na^+/K^+				

LFT				
Total Bili				
Dir. Bili				
SGOT				
SGPT				
Total Protein				
Sr. Albumin				

CXR :

USG ABDOMEN :

MAMMOGRAM :

CECT ABDOMEN

TREATMENT

OPERATIVE MANAGEMENT :

FOLLOW UP :

ஆராய்ச்சியில் பங்கேற்பவர்கான தகவல் அறிக்கை

ஆராய்ச்சி தலைப்பு

நுண்துளை பித்தப்பை நீக்க அறுவை சிகிச்சையின் போது முற்காப்பு ஆண்டிபயாடிக் சிகிச்சையின் பலனைக் கண்டறியும் ஓர் ஒப்பீட்டு ஆய்வு.

பங்கு கொள்பவரின் பெயர் :

ஆராய்ச்சி செய்பவரின் பெயர் : மரு.ஆ.சுரேஷ்குமார்

இடம் : இராஜீவ்காந்தி அரசு பொது மருத்துவமனை, சென்னை-3.

இந்த ஆராய்ச்சி/ஆய்வு/ செய்முறை/சோதனையில் தாங்கள் பங்கேற்க அழைக்கிறோம். இந்த தகவல் அறிக்கையில் கூறப்பட்டிருக்கும் தகவல்கள் தாங்கள் இந்த ஆராய்ச்சியில் பங்கேற்கலாமா வேண்டாமா என்பதை முடிவு செய்ய உதவியாக இருக்கும். இந்த படிவத்தில் உள்ள தகவல்கள் பற்றி உள்ள சந்தேகங்களை நீங்கள் தயங்காமல் கேட்கலாம்.

இந்த ஆய்வின் நோக்கம் என்ன?

பித்தப்பை கல் பிரச்சனையால் பாதிக்கப்பட்ட மக்களுக்கு நுண்துளை பித்தப்பை அறுவை சிகிச்சையின் போது ஒருமுறை இன்ட்ராவெனொஸ் ஆண்டிபயாடிக் (Intrevenous Antibiotic) சிகிச்சையே போதுமானது என்பதை நிரூபிப்பதற்கான ஓர் ஒப்பீட்டு ஆய்வு. இந்த ஆய்வில் நோயாளியின் பெயர், மருத்துவமனை இருப்பு நாட்கள், அறுவை சிகிச்சை செய்யப்பட்ட பகுதியில் நோய்த் தொற்று (Infection) ஆகியவை கவனிப்பில் கொள்ளப்படும்.

ஆய்வு முறைகள்

விரிவான நோய்க் குறிப்புகளும் மருத்துவ பரிசோதனைகளும் செய்யப்படும். நோயாளிகள் இரண்டு குழுக்களாக தன்னிச்சையாக பிரிக்கப்படுவர்.

ஆய்வுக் குழு (Study Group)

இக்குழுவினர்க்கு 1gram இன்ட்ராவெனொஸ் ஆண்டிபயாடிக் (Intrevenous Antibiotic) அறுவை சிகிச்சையின்போது மட்டும் கொடுக்கப்படும்.

ஆராய்ச்சியில் பங்கேற்பவர்கான தகவல் அறிக்கை

ஆராய்ச்சி தலைப்பு

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இந்த ஆய்வின் நோக்கம் என்ன?

பித்தப்பை கல் பிரச்சனையால் பாதிக்கப்பட்ட மக்களுக்கு நுண்துளை பித்தப்பை அறுவை சிகிச்சையின் போது ஒருமுறை இன்ட்ராவெனொஸ் ஆண்டிபயாடிக் (Intrevenous Antibiotic) சிகிச்சையே போதுமானது என்பதை நிரூபிப்பதற்கான ஓர் ஒப்பீட்டு ஆய்வு. இந்த ஆய்வில் நோயாளியின் பெயர், மருத்துவமனை இருப்பு நாட்கள், அறுவை சிகிச்சை செய்யப்பட்ட பகுதியில் நோய்த் தொற்று (Infection) ஆகியவை கவனிப்பில் கொள்ளப்படும்.

ஆய்வு முறைகள்

விரிவான நோய்க் குறிப்புகளும் மருத்துவ பரிசோதனைகளும் செய்யப்படும். நோயாளிகள் இரண்டு குழுக்களாக தன்னிச்சையாக பிரிக்கப்படுவர்.

ஆய்வுக் குழு (Study Group)

இக்குழுவினர்க்கு 1gram இன்ட்ராவெனொஸ் ஆண்டிபயாடிக் (Intrevenous Antibiotic) அறுவை சிகிச்சையின்போது மட்டும் கொடுக்கப்படும்.

கட்டுப்பாட்டு குழு (Control Group)

இக்குழுவினருக்கு 1gram இன்ட்ராவெனஸ் ஆன்டிபயாடிக் (Intrevenous Antibiotic) அறுவை சிகிச்சையின் போதும், அறுவை சிகிச்சைக்குப் பின் 5 நாட்களுக்கும் கொடுக்கப்படும்.

ஆய்வினால் நோயாளிக்கு ஏற்படும் நன்மைகள்

இந்த ஆய்வின் முடிவில் கிடைக்கும் தகவல்கள் மூலம் தேவையில்லாத ஆண்டிபயாடிக் (Antibiotic) சிகிச்சைகள் தவிர்க்கப்பட்டு ஆண்டிபயாடிக் ரெசிஸ்டென்ஸ் (Antibiotic rsistance) வராமல் தடுக்க முடியும்.

தங்களிடமிருந்து பெறப்படும் தகவல்களின் நம்பகத்தன்மை

தங்களிடமிருந்து பெறப்படும் தகவல்கள் பாதுகாக்கப்படுவதற்கான முழு உரிமையும் தங்களுக்கு உண்டு.

இந்த படிவத்தில் கையொப்பமிடுவதன் மூலம், தாங்கள் தங்களை பற்றிய விவரங்களையும், ஆய்வு விவரங்களையும் ஆராய்சியாளர், ஆய்வு நடத்தும் ஏனையோர் வரைமுறை ஒழுங்கு குழுவினர் மற்றும் சட்டத்திற்கு உட்பட்ட மருந்து கட்டுப்பாடு இயக்குநர் ஆகியோர் பார்வையிட அனுமதிக்கின்றீர்கள்.

இந்த ஆய்வில் காட்டப்படும் தகவல்கள் அறிவியல் நாளேடுகளிலோ அறிவியல் கூட்டங்களிலோ சமர்ப்பிக்கப்படும் பட்சத்தில் தங்களது அடையாளம் வெளிப்படுத்தப்படமாட்டாது.

இந்த ஆய்வில் பங்கேற்காமல் இருப்பதனால் ஏற்படும் பாதிப்பு

இந்த ஆய்வில் தாங்கள் பங்கேற்க விருப்பம் தெரிவிக்காத நிலையில் தங்களின் மருத்துவர் மற்றும் மருத்துவமனையில் தங்களுக்கு உள்ள உறவில் எந்த பாதிப்பும் ஏற்படாது. தாங்கள் சிறப்பாக கவனிக்கப்படுவீர்கள். மேலும் இதனால் தங்களுக்கு இழப்பு ஏதும் ஏற்படாது.

ஆய்வின் நடுவில் அதிலிருந்து விலகிகி கொள்ள நினைத்தால்

இந்த ஆய்வில் பங்கேற்பது தங்களின் சொந்த விருப்பமே. மேலும் ஆய்வின் நடுவில் எந்த நேரத்திலும், எக்காரணமும் கூறாமல் விலகிக் கொள்ள தங்களுக்கு முழு உரிமை உண்டு. இருப்பினும் ஆய்விலிருந்து விலகுவதற்கு முன் ஆராய்ச்சி குழுவுடன் கலந்து ஆலோசிப்பது உகந்தது என பரிந்துரைக்கப்படுகிறது.

ஆராய்ச்சியாளர் கையொப்பம் **பங்கேற்பாளர் கையொப்பம்**

ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராய்ச்சியின் தலைப்பு:

நுண்துளை பித்தப்பை நீக்க அறுவை சிகிச்சையின் போது முற்காப்பு ஆண்டிபயாடிக் சிகிச்சையின் பலனைக் கண்டறியும் ஓர் ஒப்பீட்டு ஆய்வு.

ஆராய்ச்சி செய்பவரின் பெயர் : ஆ.சுரேஷ்குமார்

ஆராய்ச்சி மையம் : ராஜீவ் காந்தி அரசு பொது மருத்துவமனை, சென்னை-600 003.

..... எனும் நான், எனக்கு கொடுத்துள்ள தகவல் தாளை படித்து புரிந்து கொண்டேன். நான் பதினெட்டு வயதை கடந்துள்ளதால், என்னுடைய சுய நினைவுடனும், முழு சுதந்திரத்துடனும், இந்த ஆராய்ச்சியில் என்னை சேர்த்துக கொள்ள சம்மதிக்கிறேன்.

1. நான் எனக்கு அளிக்கப்பட்ட ஒப்புதல் படிவத்தையும் தகவல்களையும் படித்து புரிந்துகொண்டேன்.
2. ஒப்புதல் படிவத்தில் உள்ள தகவல்கள் எனக்கு விளக்கிக் கூறப்பட்டன
3. ஆய்வின் தன்மை பற்றி எனக்கு விளக்கப்பட்டது.
4. என்னுடைய உரிமைகளையும், பொறுப்புகளையும் ஆராய்ச்சியாளர் விளக்கிக் கூறினார்.
5. நான் இதுவரை எடுத்துள்ள/எடுத்துக் கொண்டிருக்கும் அனைத்து விதமான சிகிச்சை முறைகளையும் ஆராய்ச்சியாளரிடம் கூறியுள்ளேன்.
6. இந்த ஆராய்ச்சியினால் ஏற்படும் தீமைகள் பற்றி விளக்கப்பட்டன.
7. நான் ஆராய்ச்சியாளருடன் ஒத்துழைப்பேன் என்றும் எனக்கு ஏற்படக்கூடிய அசாதாரணமான நிகழ்வுகள் பற்றியும் உடனடியாக ஆராய்ச்சியாளரிடம் தெரிவிப்பேன் என்று உறுதி கூறுகிறேன்.
8. நான் கடந்த ..... மாதங்களாக வேறு எந்தவிதமான ஆய்வுகளிலும் பங்கேற்கவில்லை.
9. எனக்கு செய்யப்படும் அனைத்து பரிசோதனைகளும் (உதாரணம்: இரத்தம் எடுத்தல்) என நோயின் தன்மையை அறிவதற்காக செய்யப்படுபவை என்பதை அறிகிறேன்
10. இந்த ஆய்விலிருந்து எப்போது வேண்டுமானாலும் எக்காரணமும் கூறாமல் என்னை விடுவித்துக் கொள்ளலாம் என்பதை அறிவேன். மற்றும் இதனால் எனக்குத் தரப்படும் சிகிச்சைக்கு எந்த பாதிப்பும் வராது என்பதை அறிவேன்.

11. ஆராய்ச்சியாளர்கள் இந்த ஆய்வில் எனது பங்களிப்பை எந்த நேரத்திலும், எக்காரணமும் கூறாமல் என் சம்மதம் இல்லாமலும் என்னை விலக்கிவிட முடியும் என்பதை அறிவேன்.

12. என்னிடம் இருந்து பெறப்படும் தகவல்களை அரசு, வரைமுறை அதிகாரிகள் ஆகியோர்களுடன் பகிர்ந்து கொள்ள ஆராய்ச்சியாளர்களுக்கு அனுமதி அளிக்கிறேன். என்னுடைய தஸ்தாவேஜ்க்களை பார்வையிட அவர்களுக்கு உரிமை உண்டு.

13. என்னிடம் பெறப்படும் தகவல்களை பொதுவாக பிரசுரிக்கப்பட்டால், என்னுடைய அடையாளம் இரகசியமாக வைக்கப்படும் என்பதை அறிவேன்.

14. எனக்கு திருப்தியளிக்கும் வகையில் எனக்குக் கேட்கப்பட்ட கேள்விகளுக்கு பதில் அளிக்கப்பட்டது.

15. இந்த ஆராய்ச்சியில் பங்கேற்க தன்னிச்சையாக முழு மனதுடன் நான் சம்மதிக்கிறேன்.

இந்த ஆய்வின் போது எனக்கு என்ன சந்தேகம் ஏற்பட்டாலும் ஆராய்ச்சியாளரை தொடர்பு கொள்ளலாம் என்பதை அறிவேன். இந்த ஒப்புதல் படிவத்தில் கையெழுத்திடுவது மூலம் இங்கு தரப்பட்டிருக்கும் அனைத்து தகவல்களும் தெளிவாக கூறப்பட்டு என்னால் முபமையாக புரிந்து கொள்ளப்பட்டது என்பதை சான்றளிக்கிறேன். இந்த ஒப்புதல் படிவத்தின் நகல் என்னால் பெற்றுக் கொள்ளப்பட்டது.

பங்கேற்பவரின் கையொப்பம்: இடம்:

கட்டை விரல் ரேகை: தேதி:

பங்கேற்பவரின் பெயர்:

விலாசம்:

ஆய்வாளரின் பெயர்: இடம்:

ஆய்வாளரின் பெயர் தேதி: